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Lamoureux et al.

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(54) **IMPLANTS INCLUDING SPACERS FOR USE IN BRACHYTHERAPY AND OTHER RADIATION THERAPY THAT RESIST MIGRATION AND ROTATION**

(75) Inventors: **Gary A. Lamoureux**, Woodbury, CT (US); **James Matons**, Newtown, CT (US); **Warren W. Johnston**, Thomaston, CT (US); **Matthew Bouffard**, Oakville, CT (US); **Warren Rice**, Watertown, CT (US)

(73) Assignee: **Eckert & Ziegler Bebig S.A.** (BE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 582 days.

This patent is subject to a terminal disclaimer.

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(51) **Int. Cl.**
A61M 36/00 (2006.01)

(52) **U.S. Cl.**
USPC **600/8**

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CPC A61F 2/0811
USPC 600/1–8; 604/285–288, 890.1–892.1; 424/422–437; 606/104, 213–221, 606/232–233
See application file for complete search history.

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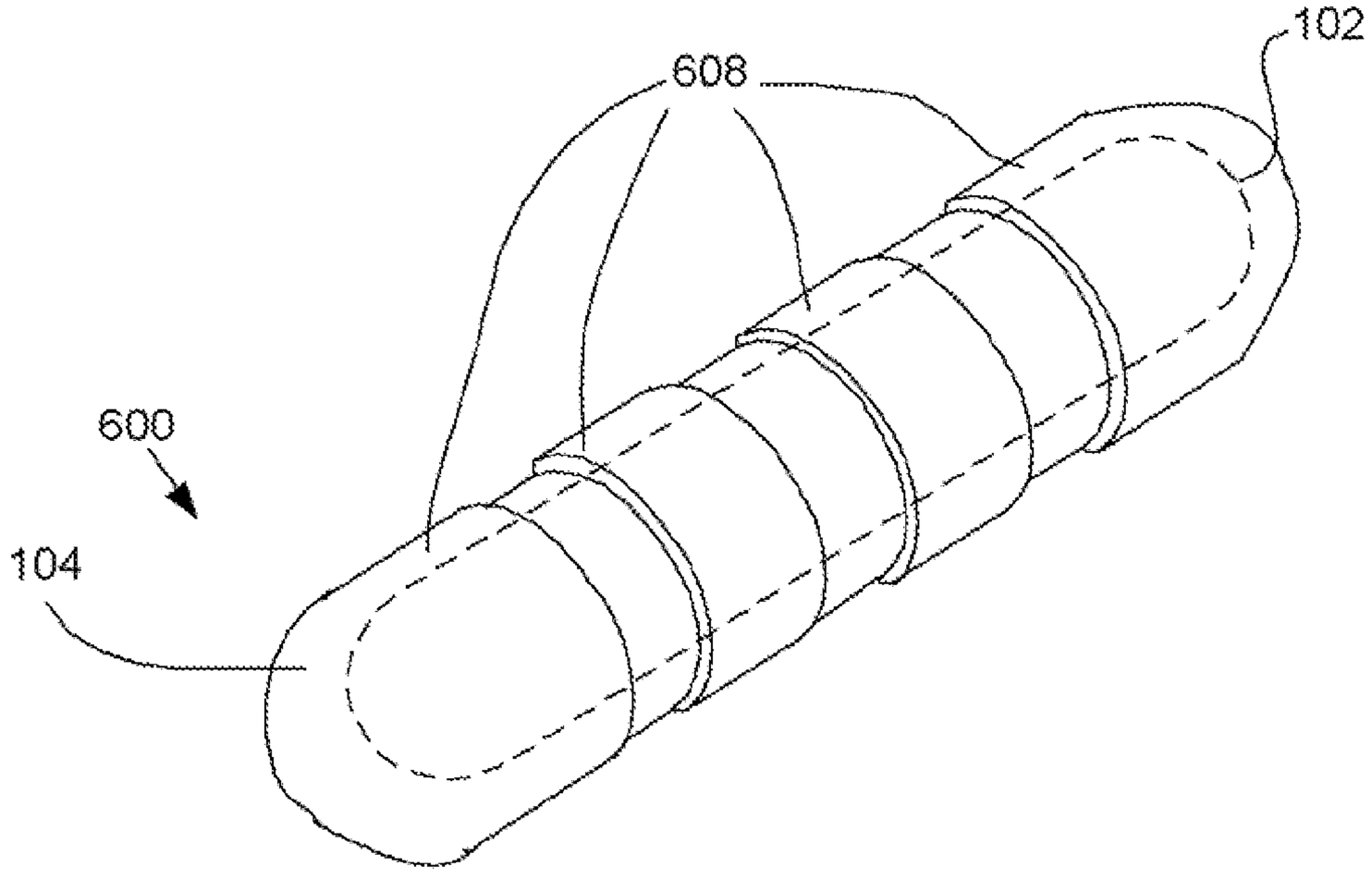
Primary Examiner — Catherine B Kuhlman
(74) *Attorney, Agent, or Firm* — Meyer IP Law Group

(57) **ABSTRACT**

A brachytherapy implant includes a plurality of protrusions to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation. Embodiments of the present invention are directed to spacers that resist migration and rotation. This abstract is not intended to be a complete description of the invention.

15 Claims, 9 Drawing Sheets



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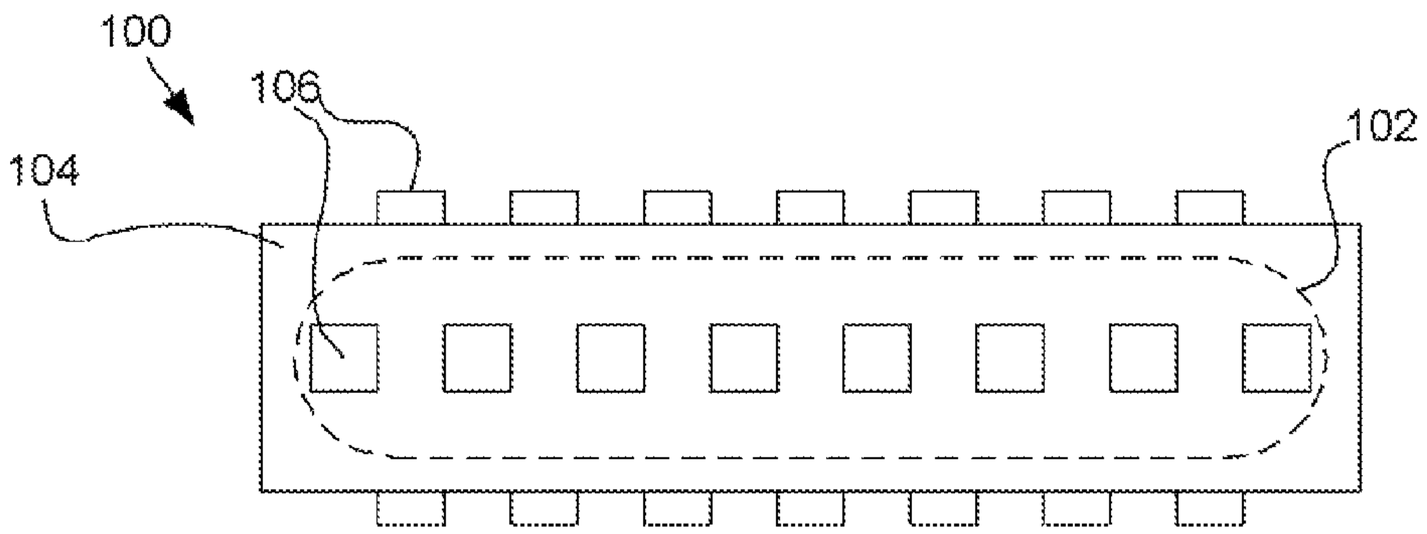

FIG. 1A

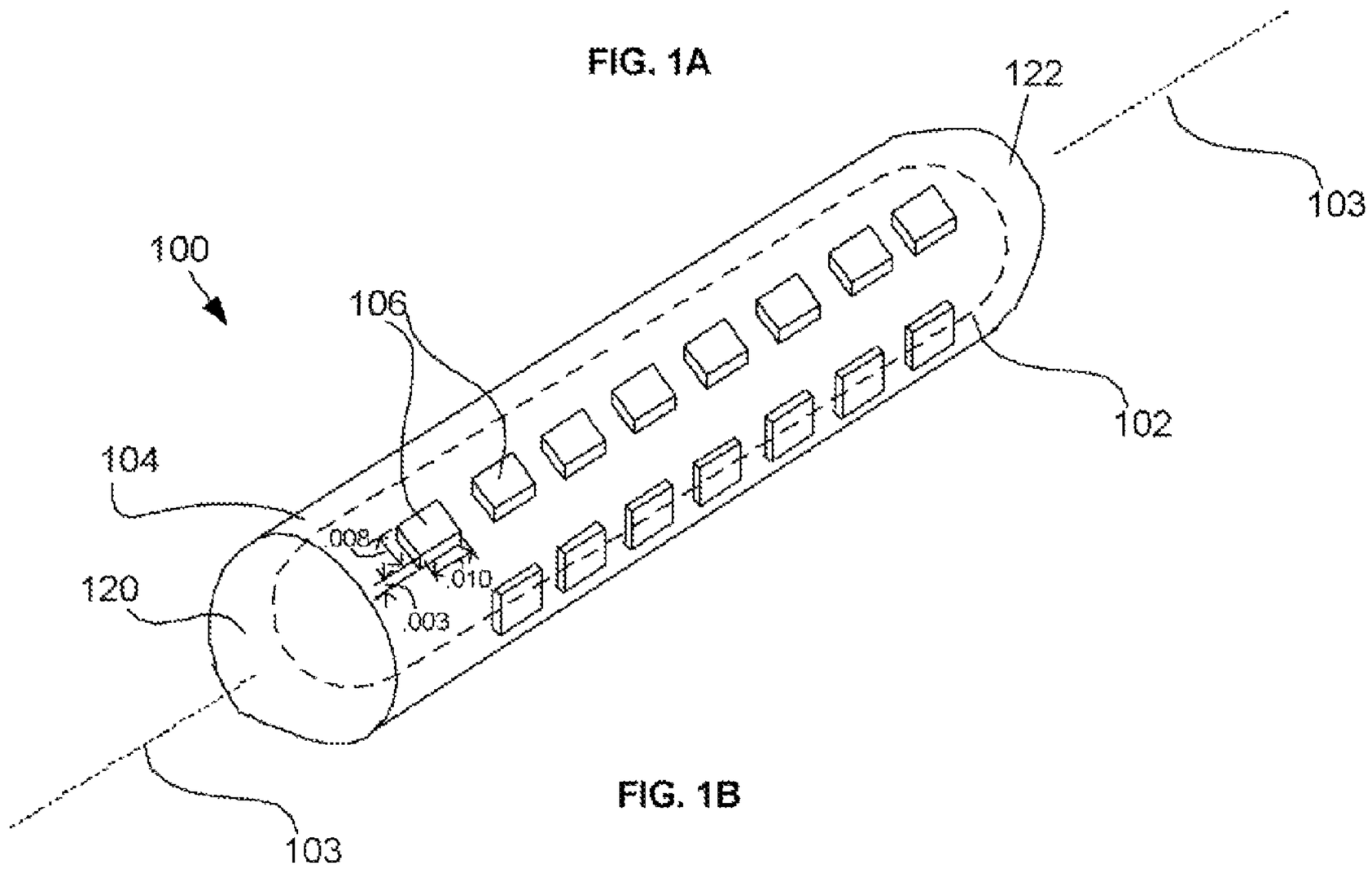

FIG. 1B

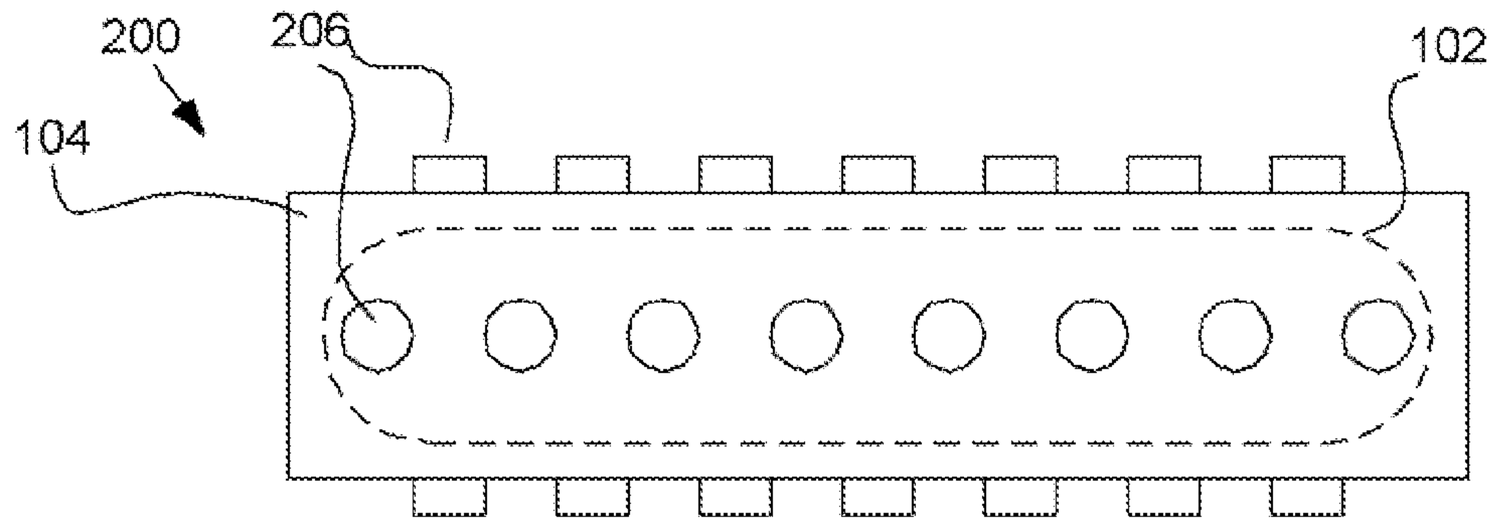

FIG. 2

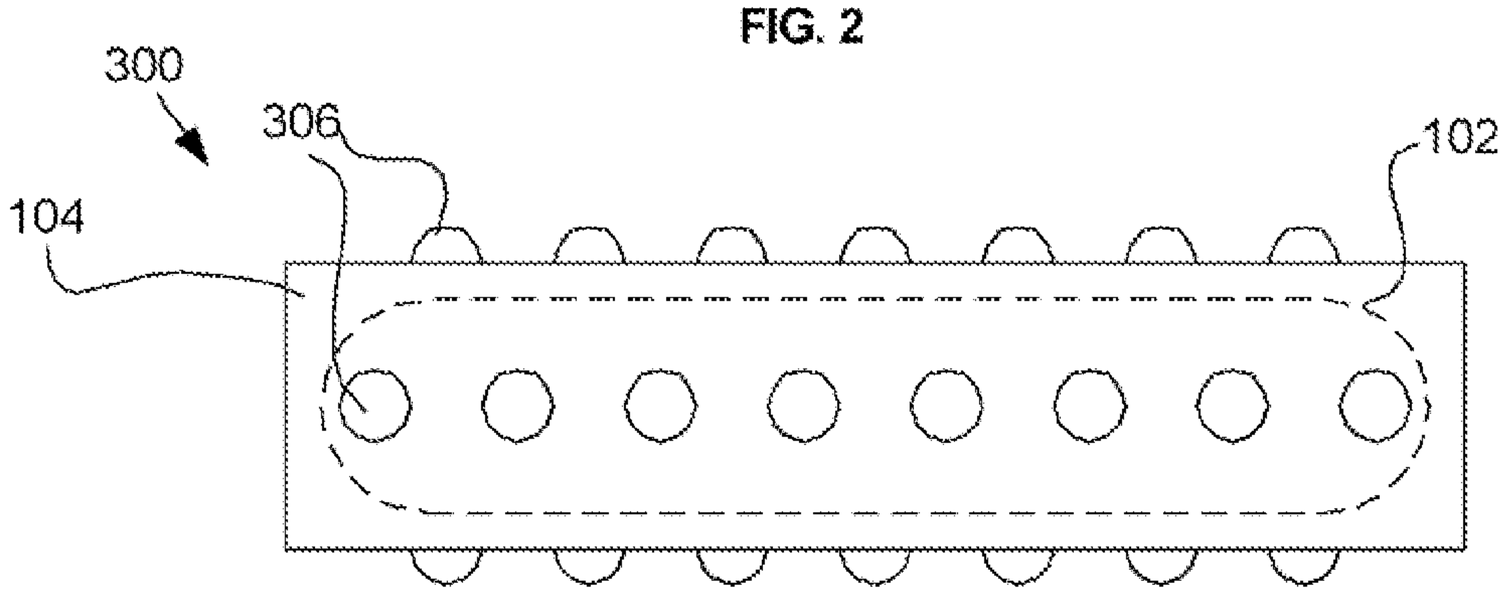

FIG. 3

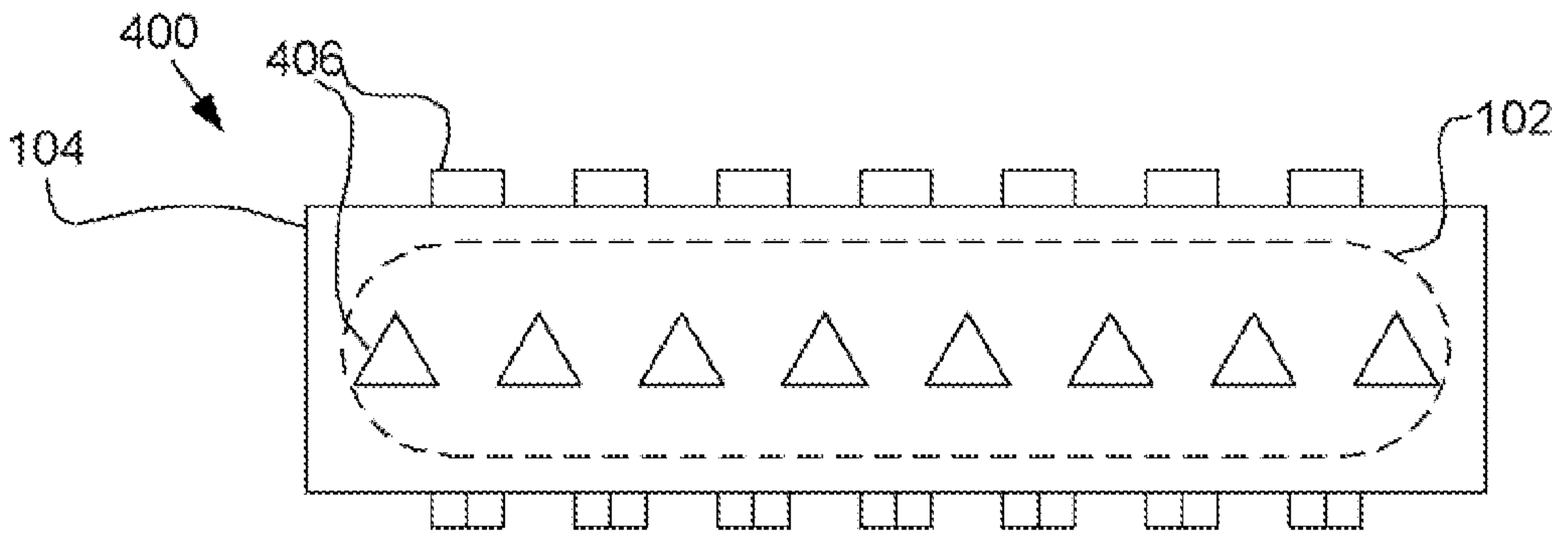

FIG. 4

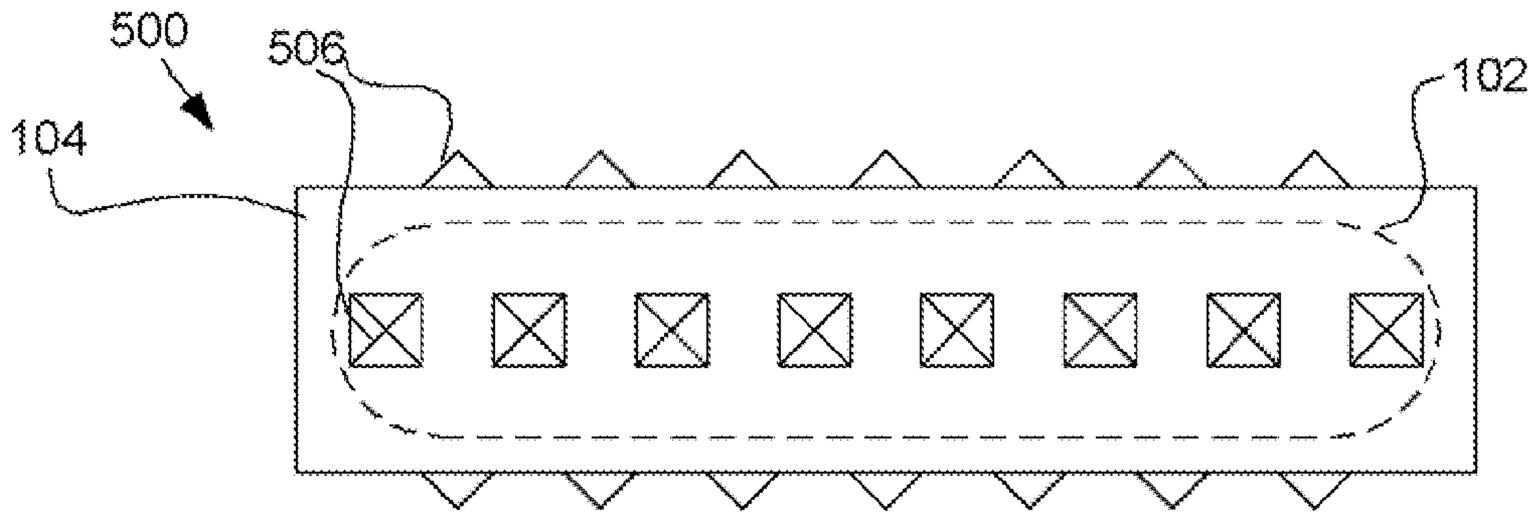

FIG. 5

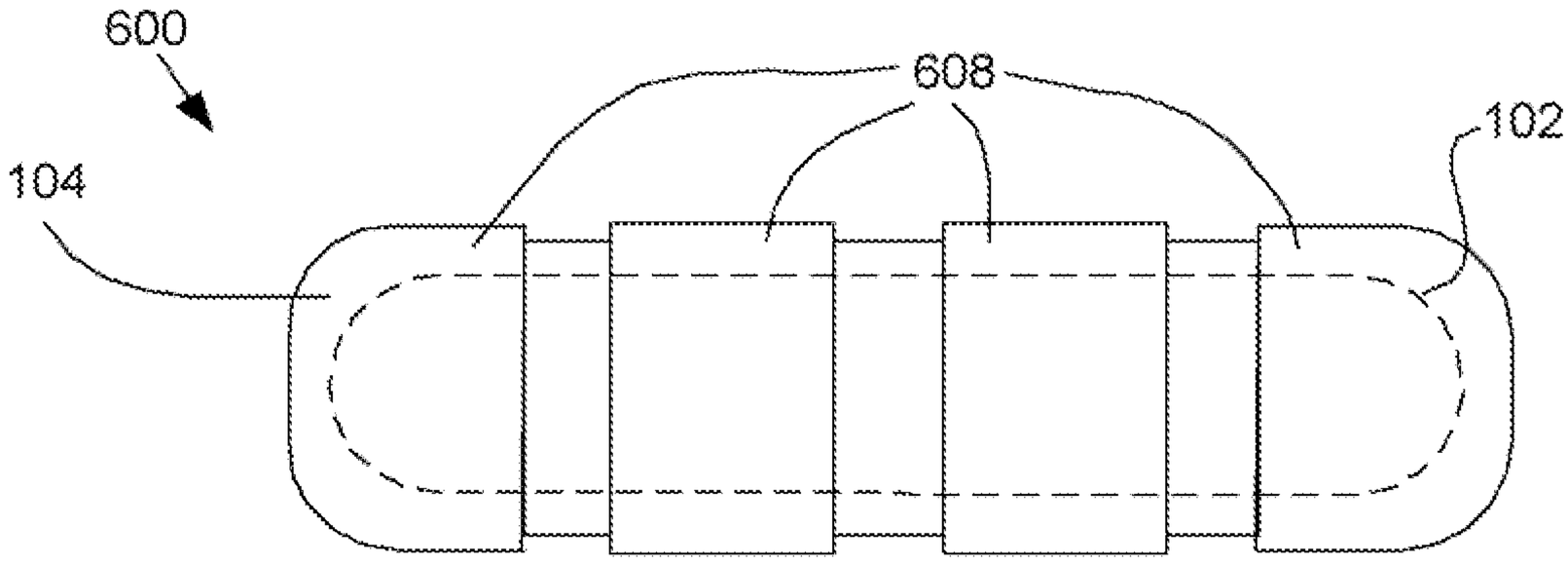

FIG. 6A

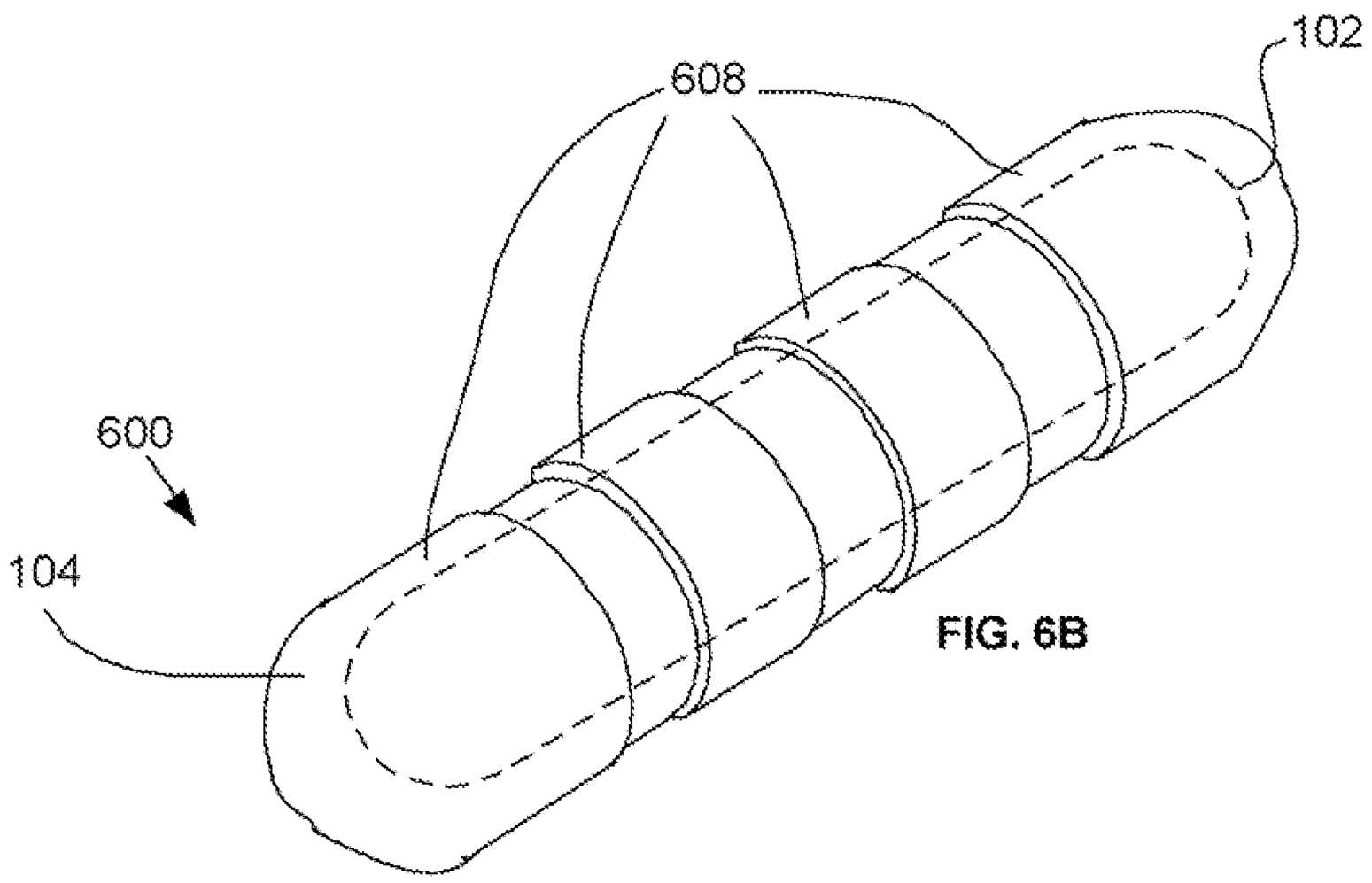

FIG. 6B

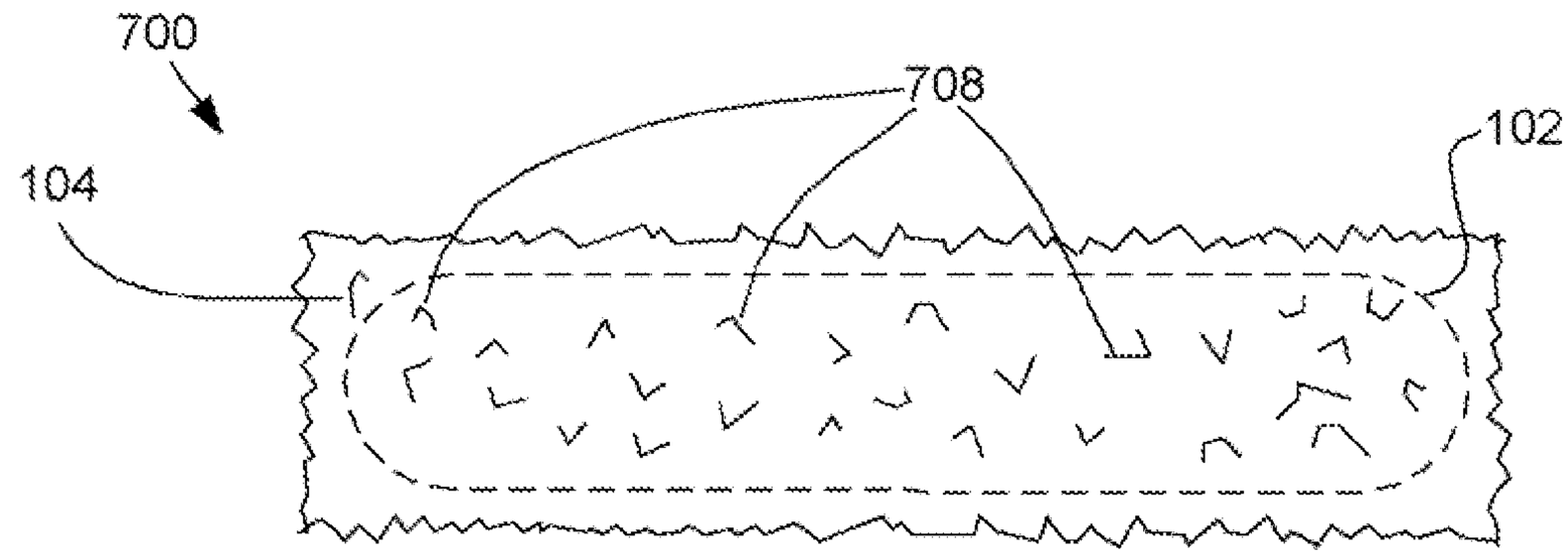

FIG. 7A

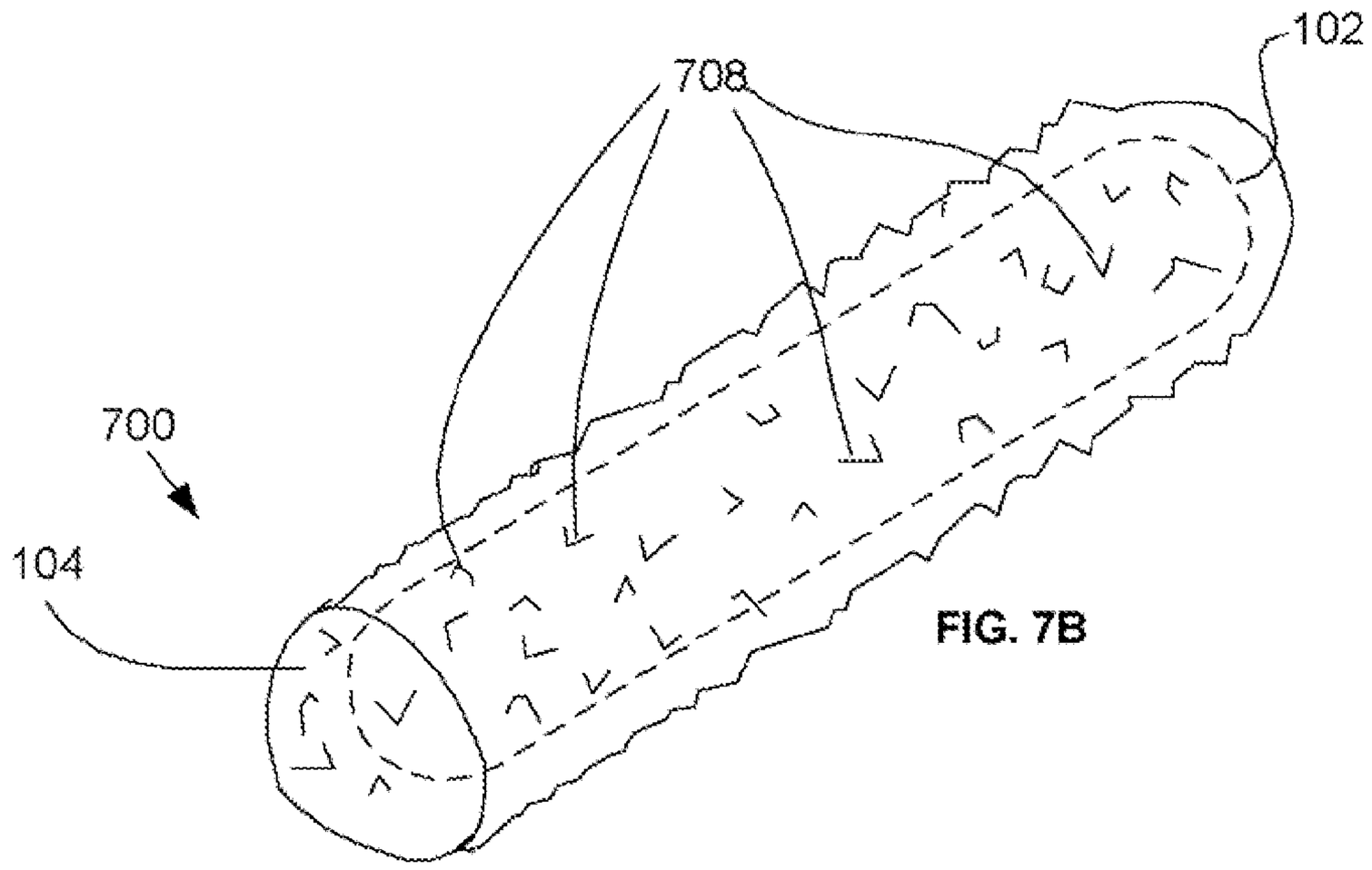

FIG. 7B

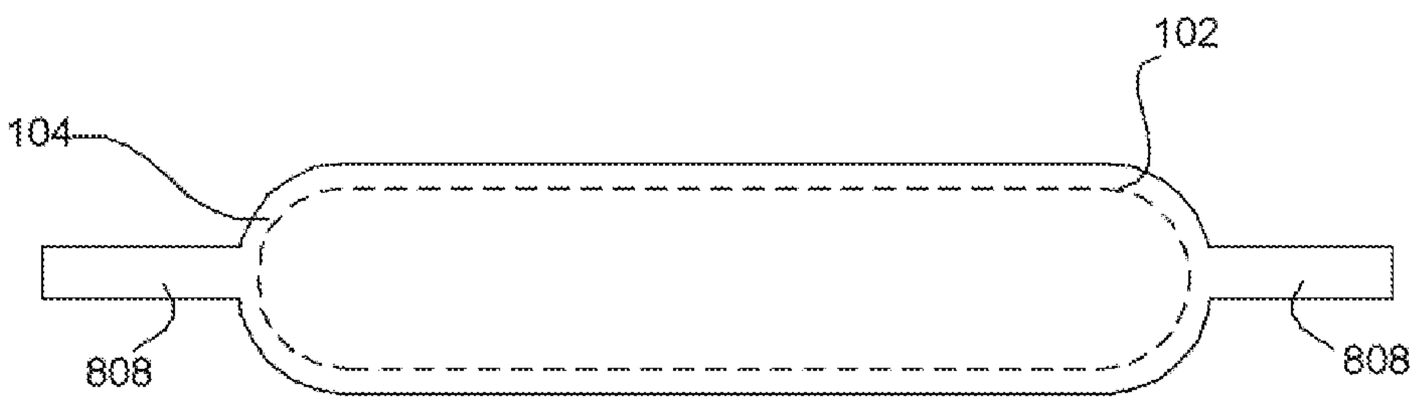

FIG. 8A

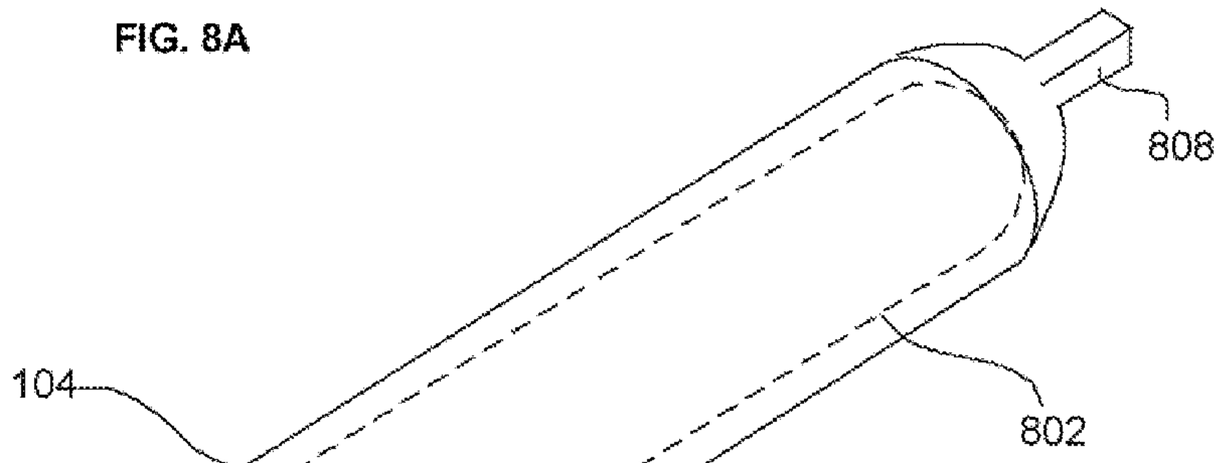

FIG. 8B

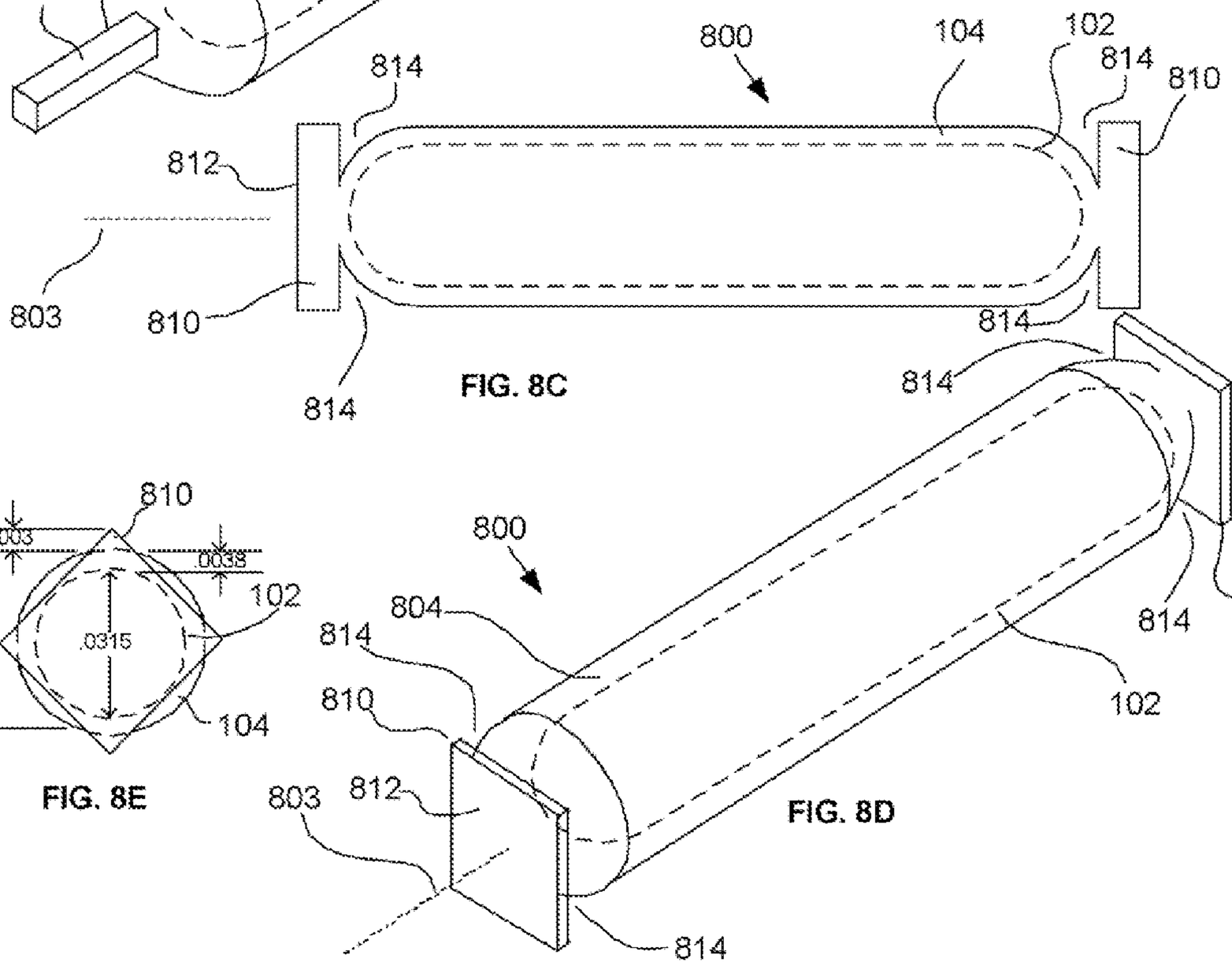

FIG. 8C

FIG. 8D

FIG. 8E

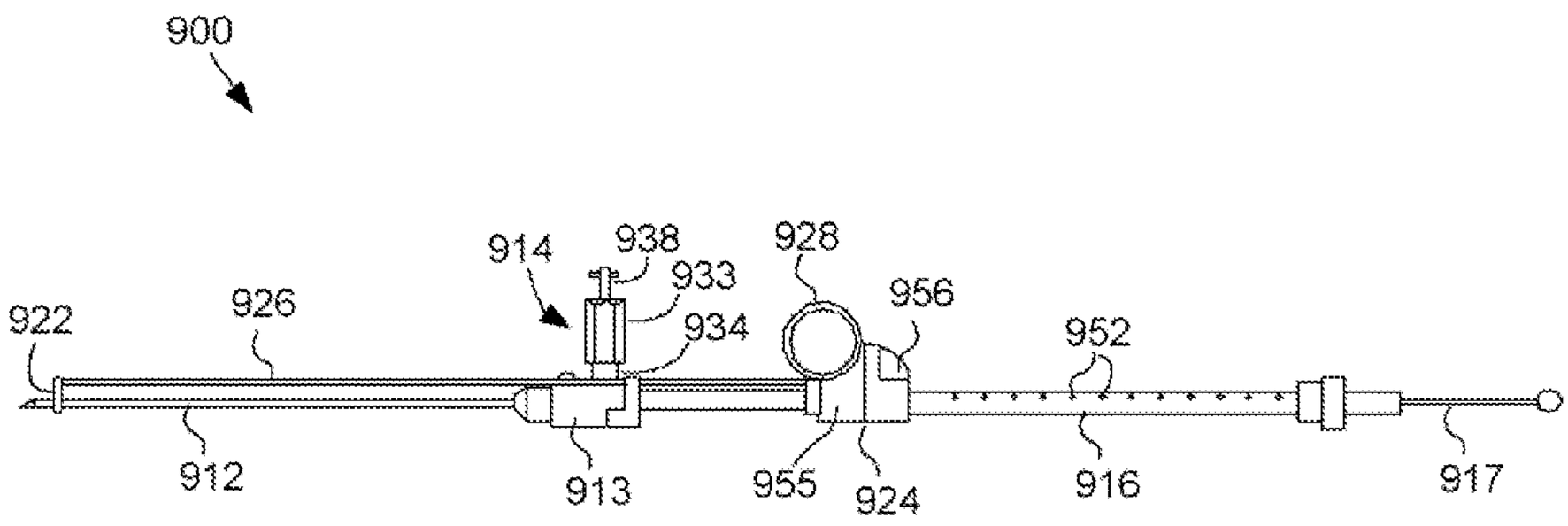

FIG. 9

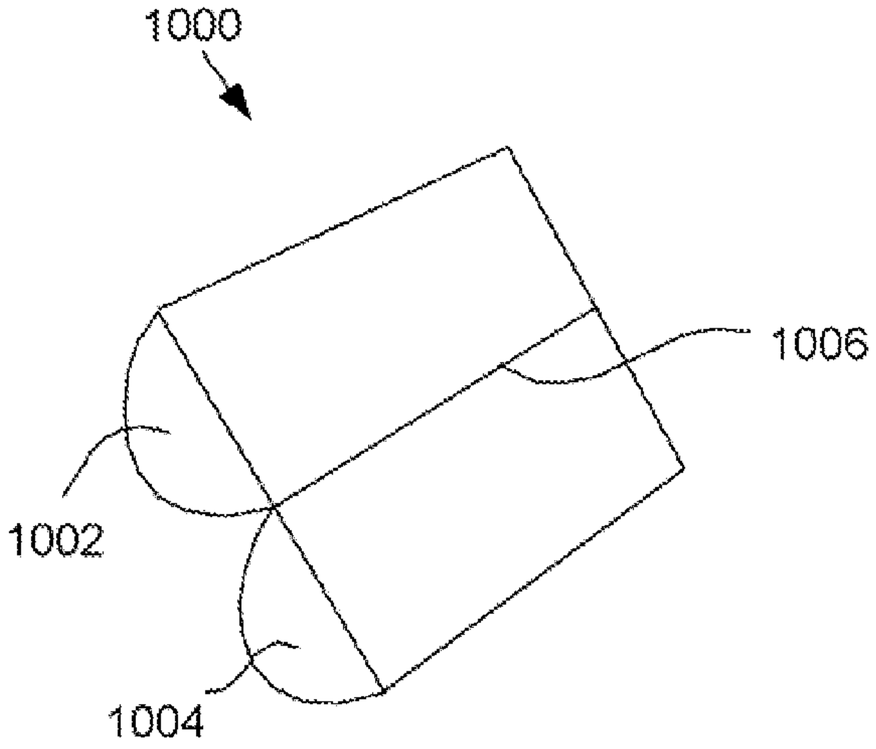

FIG. 10A

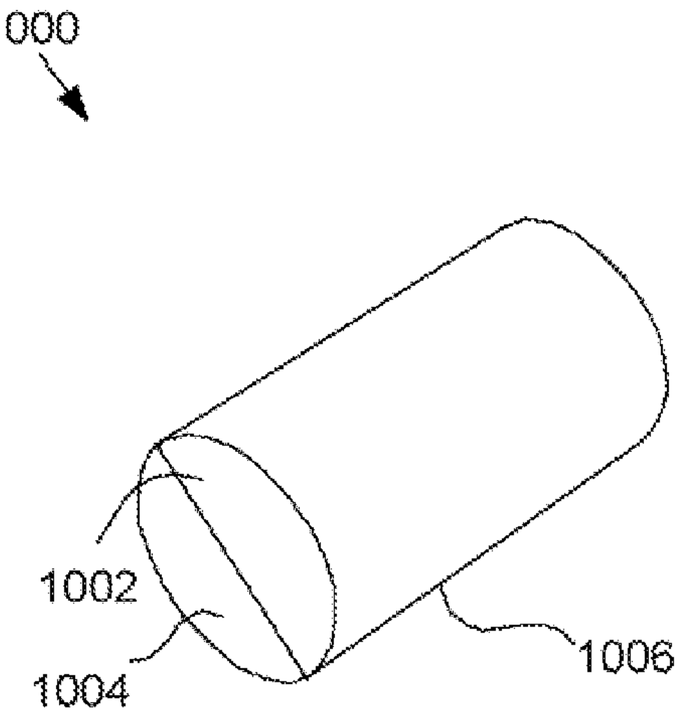

FIG. 10B

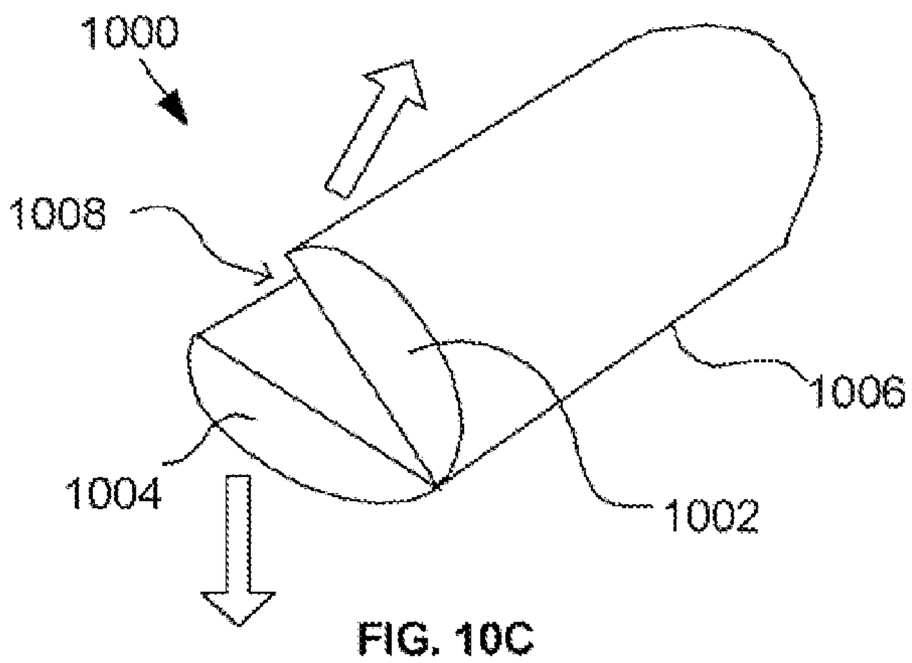

FIG. 10C

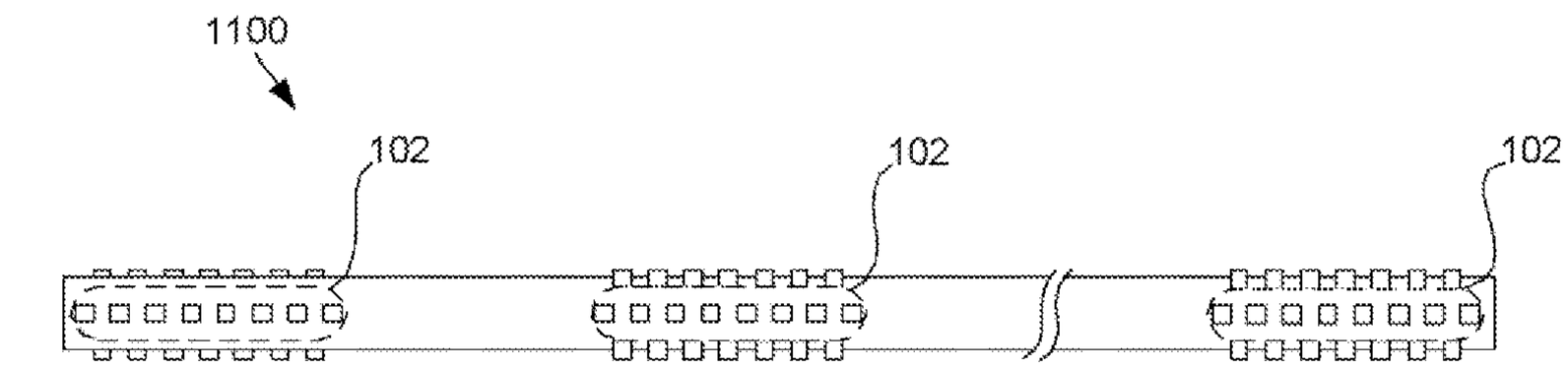

FIG. 11

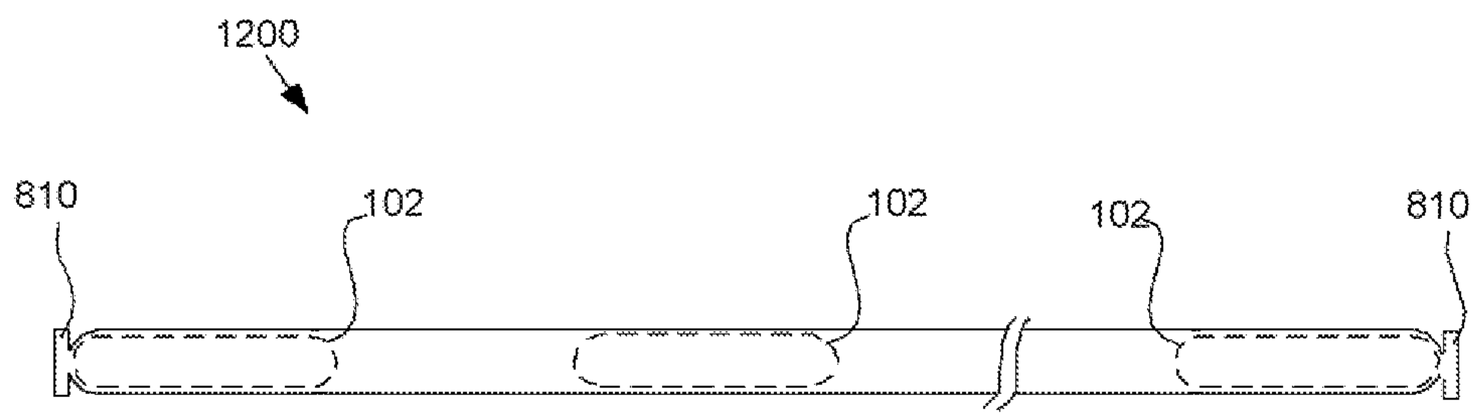

FIG. 12

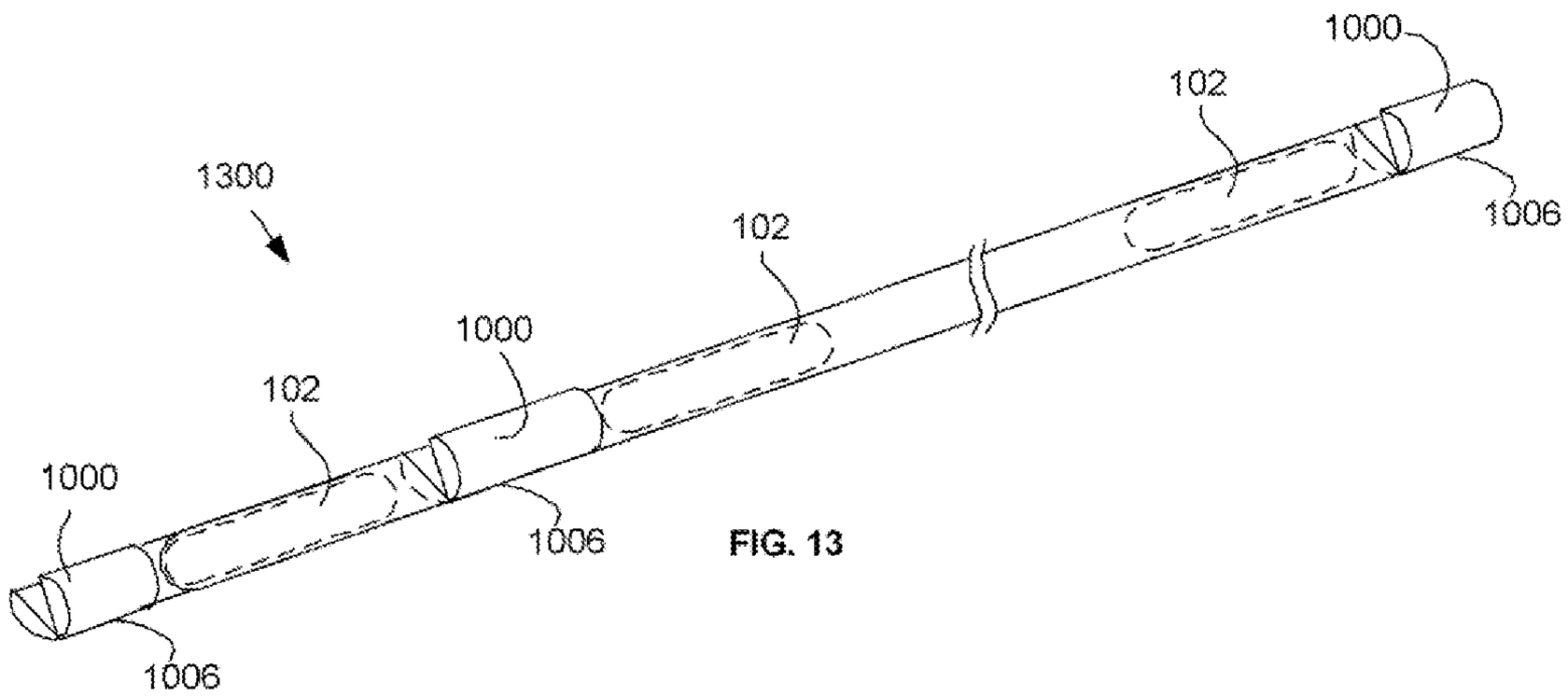

FIG. 13

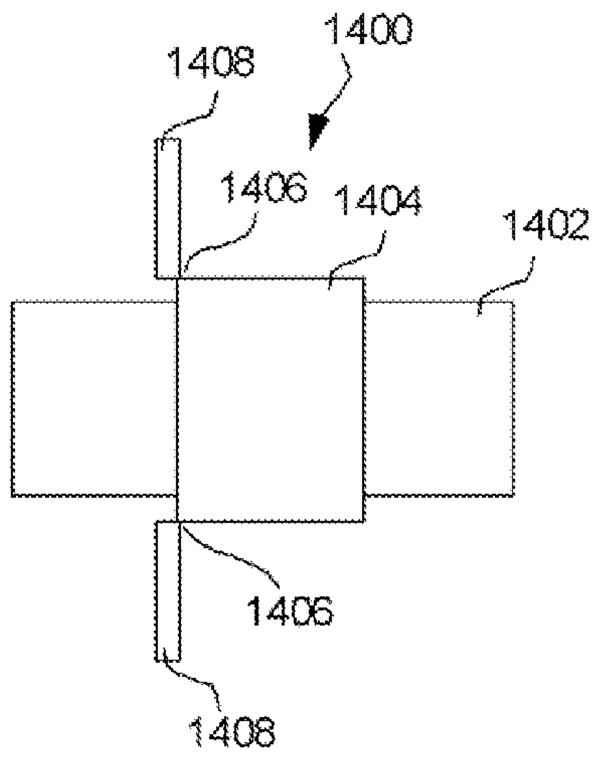

FIG. 14A

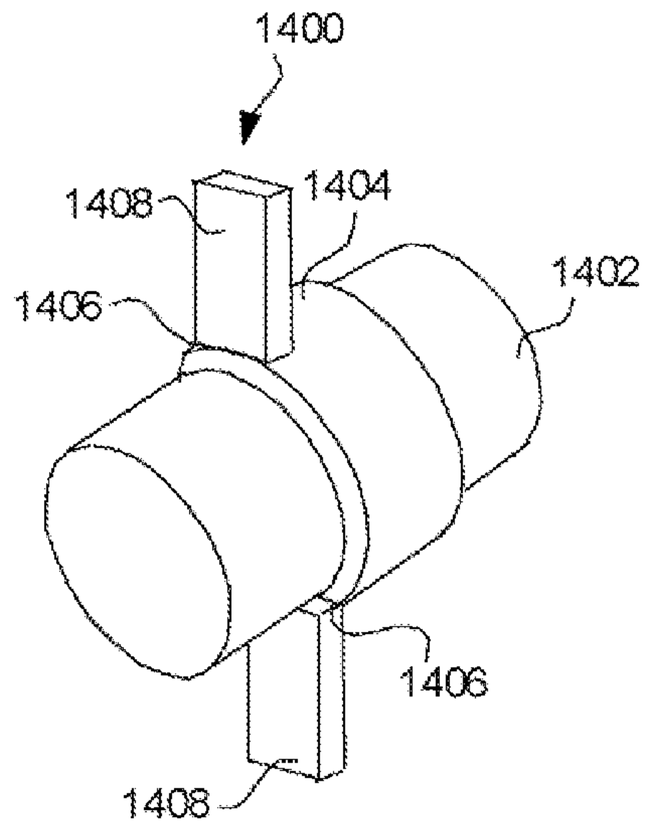

FIG. 14B

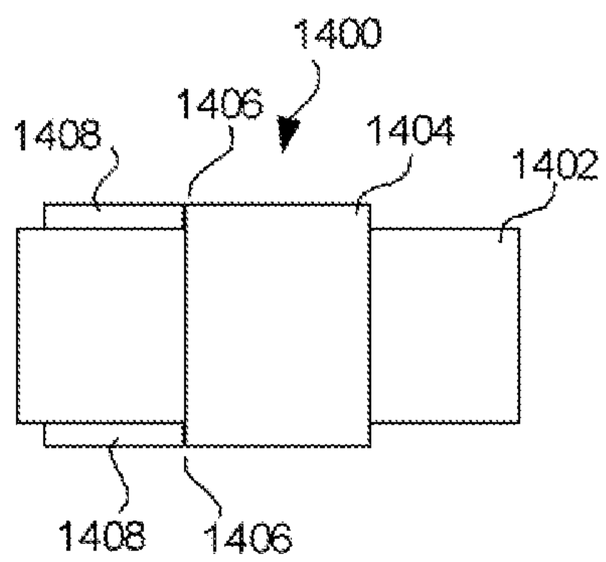

FIG. 14C

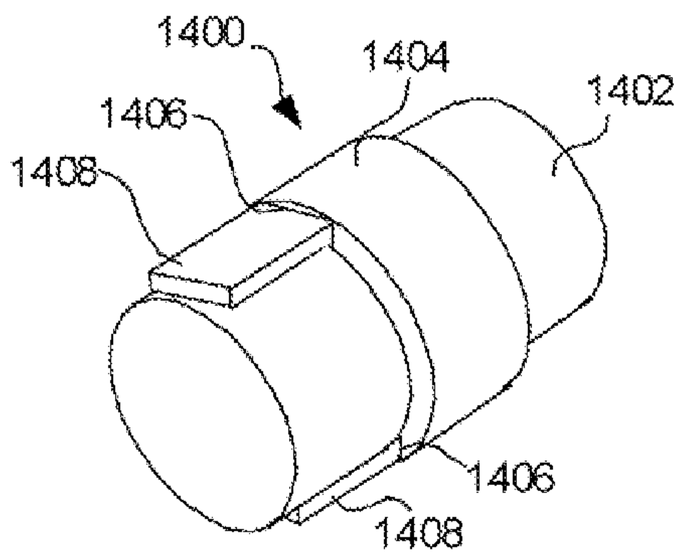

FIG. 14D

IMPLANTS INCLUDING SPACERS FOR USE IN BRACHYTHERAPY AND OTHER RADIATION THERAPY THAT RESIST MIGRATION AND ROTATION

CLAIM TO PRIORITY

This application is a continuation of U.S. patent application Ser. No. 11/187,411, filed Jul. 22, 2005, entitled "Implants for use in Brachytherapy and Other Radiation Therapy That Resist Migration and Rotation," which is incorporated herein in its entirety.

FIELD OF THE INVENTION

This invention relates to radiotherapy. More particularly, it relates to implants for use in brachytherapy, and in particular to therapeutic members, spacers and strands that are used to resist migration and rotation of radioactive sources. The invention also relates to implantable radiopaque markers that resist migration and rotation.

BACKGROUND

Brachytherapy is a general term covering medical treatment which involves placement of radioactive sources near a diseased tissue and may involve the temporary or permanent implantation or insertion of radioactive sources into the body of a patient. The radioactive sources are thereby located in proximity to the area of the body which is being treated. This has the advantage that a high dose of radiation may be delivered to the treatment site with relatively low doses of radiation to surrounding or intervening healthy tissue. Exemplary radioactive sources include radioactive seeds, radioactive rods and radioactive coils.

Brachytherapy has been used or proposed for use in the treatment of a variety of conditions, including arthritis and cancer. Exemplary cancers that may be treated using brachytherapy include breast, brain, liver and ovarian cancer and especially prostate cancer in men. For a specific example, treatment for prostate cancer may involve the temporary implantation of radioactive sources (e.g., rods) for a calculated period, followed by their subsequent removal. Alternatively, the radioactive sources (e.g., seeds) may be permanently implanted in the patient and left to decay to an inert state over a predictable time. The use of temporary or permanent implantation depends on the isotope selected and the duration and intensity of treatment required.

Permanent implants for prostate treatment include radioisotopes with relatively short half lives and lower energies relative to temporary seeds. Exemplary permanently implantable sources include iodine-125, palladium-103 or cesium-131 as the radioisotope. The radioisotope can be encapsulated in a biocompatible casing (e.g., a titanium casing) to form a "seed" which is then implanted. Temporary implants for the treatment of prostate cancer may involve iridium-192 as the radioisotope. For temporary implants, radioactive rods are often used.

Conventional radioactive seeds are typically smooth sealed containers or capsules of a biocompatible material, e.g., titanium or stainless steel, containing a radioisotope within the sealed chamber that permits radiation to exit through the container/chamber walls. Other types of implantable radioactive sources for use in radiotherapy are radioactive rods and radioactive coils, as mentioned above.

Preferably, the implantation of radioactive sources for brachytherapy is carried out using minimally-invasive techniques such as, e.g., techniques involving needles and/or catheters. It is possible to calculate a desired location for each radioactive source which will give the desired radiation dose profile. This can be done using knowledge of the radioisotope content of each source, the dimensions of the source, accurate knowledge of the dimensions of the tissue or tissues in relation to which the source is to be placed, plus knowledge of the position of the tissue relative to a reference point. The dimensions of tissues and organs within the body for use in such dosage calculations may be obtained prior to or during placement of the radioactive sources by using conventional diagnostic imaging techniques including X-ray imaging, magnetic resonance imaging (MRI), computed tomography (CT) imaging, fluoroscopy and ultrasound imaging.

During the placement of the radioactive sources into position, a surgeon can monitor the position of tissues such as the prostate gland using, e.g., ultrasound imaging or fluoroscopy techniques which offer the advantage of low risk and convenience to both patient and surgeon. The surgeon can also monitor the position of the relatively large needle used in implantation procedures using ultrasound or other imaging.

Once implanted, radioactive sources (e.g., seeds, rods or coils) are intended to remain at the site of implantation. However, the radioactive sources may on some occasions migrate within a patient's body away from the initial site of implantation. This is undesirable from a clinical perspective, as migration may lead to underdosing of a tumor or other diseased tissue and/or exposure of healthy tissue to radiation. Additionally, there have been reported incidents where a migrated seed implant has caused a pulmonary embolism. Accordingly, there is a need to reduce the tendency for radioactive sources to migrate within a patient's body.

Radioactive sources may also on some occasions rotate or twist from the original orientation at which the seed was implanted. This is also undesirable from a clinical perspective, because the radiation pattern of the sources may be directional, thereby causing underdosing or overdosing of a tumor or other diseased tissue and/or exposure of healthy tissue to radiation. Accordingly, there is also a need to reduce the tendency for radioactive sources to rotate within a patient's body.

Efforts have been made to reduce the tendency for radioactive seeds to migrate within a patient's body. For example, U.S. Pat. No. 6,632,176 (the '176 patent) discloses a radioactive seed having a biocompatible container with at least one part of a surface of the container being roughened, shaped or otherwise treated so that it is no longer smooth. According to the '176 patent, the roughening, shaping or other treatment is achieved by: forcing the seed container through a ridged or serrated dye or a threading device to impart grooves on the outer surface of the container; milling the seed container; using a wire brush, file, or sandpaper to roughen the outer surface of the container; etching using a laser or water jet cutter, or by electrolytic etching; blasting (e.g., sand blasting); or electroplating.

Disadvantages of the radioactive seeds disclosed in the '176 patent is that they are not off the shelf seeds, but rather, are custom seeds whose manufacturing cost is likely higher than that of a typical radioactive seed. Additionally, even though the '176 patent says that the treatment process should not compromise the integrity of the container, the integrity of the container may indeed be affected by the roughing, shaping and other treatments suggested in the '176 patent. Additionally, because the containers themselves are being changed, the radioactive seeds having such roughened, shaped or otherwise treated containers may be subject to government certification or re-certification. Further, the

modified containers may affect the directional radiation pattern of the seed, potentially resulting in adverse clinical results. Accordingly, it is preferred that the means of reducing the tendency for radioactive seeds to migrate and/or rotate within a patient's body overcome the above mentioned disadvantages.

When performing external beam radiation procedures such as intensity modulated radiation therapy (IMRT) and conformal radiation therapy (CRT) it is important that a target for radiation be accurately identified. To accomplish this, radiopaque markers (sometime referred to as fiducial or fiduciary markers) are often implanted into the patient at or near the target, so that the radiation can be accurately focused. Once implanted, such markers are intended to remain at the site of implantation. However, the markers may on some occasions migrate and/or rotate within a patient's body away from the initial site of implantation. This is undesirable because it is the locations of the markers that are used to determine where to focus the radiation treatments. Accordingly, there is a need to reduce the tendency for such markers to migrate and/or rotate within a patient's body.

SUMMARY OF THE INVENTION

Embodiments of the present invention are directed to therapeutic members and strands for use in brachytherapy. Such members and strands, as will be understood from the detailed description, are designed to reduce the tendency for the members and strands (and thus the radioactive sources therein) to migrate and/or rotate within a patient's body.

In one embodiment a member includes a radioactive source and a material that encapsulates the radioactive source. Such encapsulating material, which is preferably, but not necessarily, bio-absorbable, is likely polymeric or some other plastic material. An outer surface of the encapsulating material includes at least one protrusion, and preferably a plurality of protrusions, to reduce the tendency of the member to migrate and rotate within a patient's body after implantation.

In accordance with an embodiment, one or more of the protrusions extend in a radial direction (e.g., perpendicular or at an acute angle) with respect to a longitudinal axis of the radioactive source. One or more protrusions may also extend in a longitudinal direction with respect to the radioactive source. Such protrusions can have various shapes, such as, but not limited to, square, rectangular, circular, oval, triangular, pyramidal and semi-spherical, or combinations thereof.

In accordance with an embodiment, the one or more protrusions include one or more ribs that form one or more rings or a helix about a radial circumference of the radioactive source.

In accordance with another embodiment, the plurality of protrusions forms an irregular pattern on the outer surface of the encapsulating polymeric material. For example, the plurality of protrusions can form a surface that resembles a rough stucco surface.

In another embodiment, the encapsulating material is used to form an anchor mechanism that extends from at least one of the longitudinal ends of the radioactive seed to reduce a tendency of the member to migrate and rotate within a patient's body after implantation. In accordance with an embodiment, a void is formed between the anchor mechanism and the portion of the material that encapsulates the radioactive source, to allow patient tissue to enter the void after implantation.

Embodiments of the present invention are also directed to spacers, which are used to separate radioactive sources from one another, wherein the spacers include protrusions and/or anchor mechanisms, similar to those described above.

Embodiments of the present invention are also directed to strands that include protrusions and/or anchor mechanisms, similar to those described above. Such strands include a plurality of radioactive sources that are spaced apart from one another at desired intervals.

Embodiments of the present invention are also directed to spacers and strands that include portions that are biased to open after implantation, to thereby engage surrounding tissue.

Embodiments of the present invention are also directed to radiopaque markers that include protrusions and/or anchor mechanisms, similar to those described above, to reduce the tendency of the markers to migrate and rotate within a patient's body after implantation.

Embodiments of the present invention are also directed to an anchor mechanism that includes a sleeve to fit around a structure, such as a radioactive source, a thermal ablation implant, a spacer, a strand or a radiopaque marker. One or more wing is connected to the sleeve by a corresponding living hinge that enables the wing to be folded against the structure during implantation of the structure in a patient. The living hinge biases the wing such that one end of the wing moves away from the structure to engage surrounding patient tissue after implantation of the structure into a patient. This engagement of the wing with the tissue reduces a tendency for the structure to migrate and rotate after implantation.

This summary is not intended to be a complete description of the invention. Other features, aspects, objects and advantages of the invention can be obtained from a review of the specification, the figures, and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a side view of a therapeutic member according to an embodiment of the present invention; and FIG. **1**B is a perspective view of the therapeutic member shown in FIG. **1**A.

FIGS. **2-5** are side views of therapeutic members according to various embodiments of the present invention.

FIG. **6**A is a side view of a therapeutic member according to a further embodiment of the present invention; and FIG. **6**B is a perspective view of the therapeutic member shown in FIG. **6**A.

FIG. **7**A is a side view of a therapeutic member according to another embodiment of the present invention; and FIG. **7**B is a perspective view of the therapeutic member shown in FIG. **7**A.

FIG. **8**A is a side view of a member with tabs; FIG. **8**B is a perspective view of the member shown in FIG. **8**A; FIG. **8**C is a side view of the therapeutic member of FIGS. **8**A and **8**B after the tabs have been shaped into anchor mechanisms; FIG. **8**D is a perspective view of the member shown in FIG. **8**C; and FIG. **8**E is an end view of the therapeutic member shown in FIGS. **8**C and **8**D.

FIG. **9** is a side view of an exemplary applicator that can be used to implant therapeutic members of the present invention into a patient's body.

FIG. **10**A is a perspective view of a spacer according to an embodiment of the present invention, in an open position; FIG. **10**B is a perspective view of the spacer in FIG. **10**A in a closed position; and FIG. **10**C is a perspective view of the spacer of FIGS. **10**A and **10**B in a partially opened position.

FIG. **11** is a side view of a strand according to an embodiment of the present invention.

FIG. **12** is a side view of a strand according to another embodiment of the present invention.

FIG. **13** is a perspective view of a strand that includes portions which are biased to open after implantation, and thereby engage tissue surrounding the strand, to prevent migration and rotation of the strand.

FIG. **14**A is a side view illustrating an anchor mechanism according to an embodiment of the present invention, it its closed position; FIG. **14**B is a perspective view of the anchor mechanism of FIG. **14**A, in its closed position; FIG. **14**C is a side view of the anchor mechanism of FIGS. **14**A and **14**B, in its open position; and FIG. **14**D is a perspective view of the anchor mechanism of FIGS. **14** A-C, in its open position.

DETAILED DESCRIPTION

Embodiments of the present invention relate to therapeutic members for use in treatments such as brachytherapy. As shown in FIGS. **1**A and **1**B, each member **100** includes a radioactive source **102** (shown in dashed line) and a material **104** that encapsulates the radioactive source **102**. The radioactive source **102** can be a radioactive seed, a radioactive rod, or a radioactive coil, but is not limited thereto. The material **104** is preferably, but not necessarily, bio-absorbable. In accordance with an embodiment, the material **104** is also bio-adherent. Additionally, the material **104** is preferably a polymeric material or some other plastic. Also shown in FIG. **1** is that an outer surface of the encapsulating material **104** includes protrusions **106** to reduce a tendency of the member **100** to migrate and rotate within a patient's body after implantation. Also shown in FIG. **1**B (in dotted line) is a longitudinal axis of the radioactive source **102**, which is also the longitudinal axis of the therapeutic member **100**. The overall shape of the therapeutic member **100**, excluding the protrusions **106**, can be cylindrical with flat ends **120** and **122**, cylindrical with rounded (e.g., bullet shaped) ends **120** and **122** or rectangular, but is not limited thereto.

The protrusions that are used to reduce a tendency of the member to migrate and rotate can be of any number of different shapes and sizes, or combinations thereof. For example, in FIGS. **1**A and **1**B the protrusions **106** are shown as being square or rectangular knobs that cause the outer surface of the therapeutic member **100** to resemble a knobby tire. The protrusions **106** can form a plurality of rows (e.g., four rows) which are regularly spaced about the member **100**, e.g., with each row extending in a direction that is 90 degrees from the adjacent rows. Alternatively, the protrusions can protrude in a more random or irregular fashion.

Exemplary dimensions for one of the protrusions **106** in FIG. **1**B is shown as being 0.010×0.008×0.003 inches. All of the protrusions **106** can have similar dimensions, or the dimensions of the protrusions may vary. For example, it is possible that the protrusions within a row have similar dimensions, but the dimensions differ for different rows. For a more specific example, another row of protrusions **106** have dimensions of 0.006×0.005×0.002 inches. These are just a few examples. One of ordinary skill in the art will appreciate from this description that the protrusions can have other dimensions while being within the scope of the present invention.

Preferably, the protrusions extend at least 0.002 inches so that they can sufficiently grip into patient tissue (analogous to a knobby tire gripping soft dirt). The protrusions **106** can extend radially from the therapeutic member **100**. For example, in the embodiments shown, the protrusions **106** extend in directions that are generally perpendicular to the longitudinal axis **103** of the therapeutic member **100** and the source (e.g., seed) **102** therein. The protrusions **106** may alternatively or additionally extend at other angles with respect to the longitudinal axis **103**. For example, protrusions may extend at 45 degrees with respect to the longitudinal axis **103**. In a specific embodiment, each half of the member **100** can have protrusions **106** at a 45 degree angle facing towards the middle of the member **100**, or towards the ends of the member **100**. Various other angles, and combinations of angles, are also possible.

FIGS. **1**A and **1**B, and FIGS. **2-5** discussed below, the protrusions are shown as extending from the length of the therapeutic member. However, the protrusions may also extend from the longitudinal ends of the therapeutic member.

In another embodiment, shown in FIG. **2**, the protrusions **206** of a therapeutic member **200** are cylindrical. In still another embodiment, shown in FIG. **3**, a therapeutic member **300** includes protrusions **306** that resemble bumps or semi-spheres. In the embodiment shown in FIG. **4** the protrusions **406** of a therapeutic member **400** are triangular, and in the embodiment of FIG. **5** the protrusions **506** of a therapeutic member **500** are pyramidal. These are just a few examples of the shapes of the protrusions. One of ordinary skill in the art reading this description would appreciate that other shapes are also possible. It should also be understood that a therapeutic member of the present invention can include protrusions of numerous different shapes, including, but not limited to, the shapes shown in FIGS. **1-5**. While in the FIGS. the various protrusions are shown as having a common orientation, it is also within the scope of the present invention that the protrusions have different orientations. For example, in FIG. **5**, different triangular protrusions **506** can have different orientations.

In a further embodiment, shown in FIGS. **6**A and **6**B, the protrusions are ribs **608** that encircle the underlying source **102**. Four ribs **608** are shown in FIGS. **6**A and **6**B. However, it should be understood that more or less ribs **608** can be included. It should also be understood the ribs can be helical (i.e., spiral). In one specific embodiment, the ribs can form counter balancing screw threads (i.e., opposing helixes). For example, the threads on one half of the member can be right hand threads, while the threads on the other half of the member can be left hand threads.

In another embodiment, the plurality of protrusions can form an irregular pattern on the outer surface of the encapsulating polymeric material **104**. For example, the protrusions can form what resembles a rough stucco like surface, e.g., as shown in FIGS. **7**A and **7**B.

In the embodiments where the radioactive sources **102** are radioactive seeds, the seeds **102** can be of various types having low energy and low half-life such as Iodine seeds, known as I-125 seeds, including a welded titanium capsule containing iodine 125 adsorbed on a silver rod, or Palladium 103 seeds. Seeds may also have there isotope adsorbed on ceramic beads, resin beads, silver beads, graphite pellets, porous ceramic rods, copper cores, etc. Seed can have various different shapes, such as, but not limited to, cylindrical with flat ends, cylindrical with rounded (e.g., bullet shaped) and spherical. Exemplary dimensions of a seed **102** are 0.18 inches in length and 0.0315 inches in diameter. Exemplary seeds are listed below in Table 1, but embodiments of the present invention should not be limited to the seeds listed therein.

TABLE 1

Seed Manufacturers and Common Types of Seeds

MANUFACTURER	SEED NAME
IODINE^{125}	
Amersham 6711	OncoSeed
Amersham 6733	EchoSeed
Amersham 7000	RAPID Strand
North American Scientific	IoGold
Best Industries	BEST Iodine-125
Bebig	Symmetra
Mills Biopharmaceuticals	ProstaSeed
Syncor	PharmaSeed
International Isotopes	IsoStar
Implant Sciences	I-Plant
International Brachytherapy	InterSource-125
IsoAid	Advantage I-125
Source Tech	STM1251
DRAXIMAGE, Inc.	BrachySeed
PALLADIUM^{103}	
North American Scientific	Pd Gold
Theragenics	Theraseed 200
Best Industries	BEST Palladium-103
International Brachytherapy	InterSource 103

Alternatively, seeds **102** can be manufactured using iridium 192, cesium 131, gold 198, yttrium 90 and/or phosphorus 32. Further radioactive isotopes used to manufacture seeds are not limited to these examples, but can include other sources of different types of radiation.

In addition it is to be understood that other types of seeds can be used. For example, seeds such as those described in U.S. Pat. No. 6,248,057, which is incorporated herein by reference, can be used with the present invention. These seeds include radiation delivery devices, drug delivery devices, and combinations of radiation and drug delivery devices in the form of beads, seeds, particles, rods, gels, and the like. These particular seeds are absorbable wherein the radiation member or drug delivery member is contained within, for example, absorbable polymers such as those listed below or in the above-referenced patent. In such seeds, the bio-absorbable structure can have a predefined persistence which is the same as or substantially longer than a half life of the radioactive member contained in the bio-absorbable structure. These above bio-absorbable seeds can be used in the same manner as the seeds described herein with respect to the invention. As mentioned above, the radioactive sources **102** need not be seeds. For example, the radioactive sources **102** can be rods, e.g., metallic rods coated with a radioactive isotope such as palladium **103**, etc. The radioactive sources **102** may also be radioactive coils, such as those described in U.S. Pat. No. 6,419,621, which is incorporated herein by reference, and those available from RadioMed Corporation of Tyngsboro, Mass., under the trademarks GENETRA and RADIO COIL. In accordance with an alternative embodiment, rather than using a radioactive source, an implant that utilizes thermal ablation to treat cancer can be used. One such implant, which is marketed under the trademark ThremoRod, and is available from Ablation Technologies of San Diego, Calif., is a permanently implantable cobalt-palladium alloy rod that produces heat (e.g., 70° C.) through oscillation of a magnetic field. In such embodiments, the material **104** is used to encapsulate the thermal ablation implant and to form protrusions, as described above, to resist migration and rotation of the implant.

To allow X-ray detection of the radioactive sources, the radioactive sources can include a radiopaque marker, which is typically made of a dense, high atomic number material, such as gold or tungsten, which can block the transmission of X-rays so that the radioactive source can be detected by using X-ray imaging techniques. This can be accomplished, e.g., by including a ball, rod or wire constructed of a dense, high atomic number material, such as gold or tungsten, within the container of a radioactive source (e.g., seed). Alternatively, the radioactive seed (or other source) can be at least partially coated with a radiopaque material.

The therapeutic members of the present invention can be manufactured in various manners. For example, a molding process, such as compression molding or injection molding can be used. In one example, a radioactive source is placed into an embossing mold that includes the inverse (i.e., negative) of the pattern of projections that is to be embossed on the outer surface of the polymeric material. Before or after the source (e.g., seed) is placed in the mold, a bio-absorbable polymer or some other plastic material is introduced into the mold at a temperature that is above the melt point of the material such that the material flows around the seed within the mold cavity. The material is then allowed to set within the mold, e.g., by cooling the mold. After the material has set, the mold is opened, and the finished therapeutic member with a plurality of polymeric projections is removed. In other embodiments, an encapsulating material is molded around the seed, and then the protrusions are produced in a secondary process, e.g., by machining, crimping or otherwise altering the shape of the encapsulating material to form protrusions. In still other embodiments, the protrusions are formed in the encapsulating material prior to the seed being placed into the material. In still further embodiments, the protrusions can be doughnut shaped pieces that are slid over the radioactive source implant. These are just a few examples. Other techniques for producing the protrusions are also within the scope of the present invention.

For the embodiment of FIGS. **7**A and **7**B, where the outer surface or the member **700** resembles a rough stucco surface, a mold can include purposeful protrusions, or can simply be a rough surface that was formed when casting or otherwise manufacturing the mold. Typically, the metal of the mold would be machined such that a member produced using the mold would have a generally smooth surface. However, in accordance with an embodiment of the present invention the mold is left rough, so that the member **700** formed using the mold would have random protrusions.

In another embodiment, a radioactive source **102** is encapsulated within a polymeric material, and then protrusions are attached to the outer surface of the encapsulating material in a secondary process. For example, while the outer surface of the encapsulating material is tacky, particles or strands can be attached to the outer surface to thereby form the protrusions. The outer surface of the encapsulating material can be made tacky by heating the material, coating the material with a bio-compatible adhesive, or otherwise wetting the material. The particles or strands can then be attached to the outer surface of the material, e.g., by sprinkling the particles or strands onto the outer surface, or rolling the encapsulated source in the particle or strands. Such particles or strands should be bio-compatible, and can also bio-absorbable. The particle or strands can be made of the same material as the material **104** that encapsulates the radioactive source **102**, but this is not necessary. It is also possible that the container of the radioactive source be coated with a bio-compatible adhesive, and that the particles or strands are directly attached to the container of the radioactive source, to thereby form the protrusions that resist migration and rotation.

In another embodiment, the material **104** can be molded or otherwise formed around a source **102** such that a tab **808** extends longitudinally (i.e., axially) from each longitudinal end of the encapsulated radioactive source **102**, as shown in FIGS. **8**A and **8**B. In a secondary process, each tab **808** is heated and formed into an anchor mechanism **810**, shown in FIGS. **8**C and **8**D. More specifically, the main body of the member **800** (within which the seed **102** is located) can be held in place while each tab **808** is melted into a desired shape by pushing against the tab **808** with a heated surface or mold that is moved toward the main body of the member. The heated surface or mold that is used to melt the tab **808** can simply be a flat surface, which will cause the anchor mechanism **810** to have an amorphous shape. Alternatively, the mold that is used to melt the tab **808** can be shaped to cause the anchor mechanism **810** to have a specific shape, such as a square, as shown in FIGS. **8**C and **8**D. FIG. **8**E, which is an end view of the member **800** shown in FIGS. **8**C and **8**D, includes exemplary dimensions in inches.

In FIGS. **8**C-**8**E, the anchor mechanism **810** is square shaped. In alternative embodiments the anchor mechanisms can have other shapes. For example, the anchor mechanism **810** can be amorphous, rectangular, triangular, trapezoidal, etc. In accordance with specific embodiments, an outer surface **812** of the anchor mechanism **810** is generally perpendicular to the longitudinal axis **103** of the radioactive source **102**, as shown in FIGS. **8**C and **8**D. A void or groove **814** is formed between the main portion of the member and the anchor mechanism **810**, thereby allowing patient tissue to occupy this void **814** to reduce the tendency for the member **800**, and the radioactive source **102** therein, to migrate or rotate.

It is preferred that the anchor mechanism **810** be located at each longitudinal end of the therapeutic member **800**, as shown in FIGS. **8**C and **8**D. However, in alternative embodiments the anchor mechanism **810** can be located at only one of the longitudinal ends of the member. In FIGS. **8**A-**8**E the outer surface of the main body of the therapeutic member **800** is shown as being generally cylindrical and smooth. However, this need not be the case. The embodiments of FIGS. **1**-**7** discussed above can be combined with the embodiments of FIGS. **8**A-**8**E. For example, a same mold that is used to form the protrusions of FIGS. **1**-**7** can be used to form the tabs **808**, which can then shaped into the anchor mechanisms **810** in a secondary process after the members have been removed from the mold. In still another embodiment, the anchor mechanisms **810** can be formed by an embossing mold similar to that used to form the protrusions of FIGS. **1**-**7**.

The radioactive sources **102** can be coated with or contain a drug and/or hormone. Alternatively, a drug and/or hormone can be included in the encapsulating material **104** that is used for form the protrusions or anchor mechanisms of the present invention.

Example types of materials **104** that are bio-absorbable include, but are not limited to, synthetic polymers and copolymers of glycolide and lactide, polydioxanone and the like. Such polymeric materials are more fully described in U.S. Pat. Nos. 3,565,869, 3,636,956, 4,052,988 and European Patent Publication No. 0030822, all of which are incorporated herein by reference. Specific examples of bio-absorbable polymeric materials that can be used to produce the therapeutic members of embodiments of the present invention are polymers made by Ethicon, Inc., of Somerville, N.J., under the trademarks "MONOCRYL" (polyglycoprone 25), "MAXON" (Glycolide and Trimethylene Carbonate), "VICRYL" (polyglactin 910) and "PDS II" (polydioxanone).

Other exemplary bio-absorbable materials include poly (glycolic acid) (PGA) and poly(-L-lactic acid) (PLLA), polyester amides of glycolic or lactic acids such as polymers and copolymers of glycolate and lactate, polydioxanone and the like, or combinations thereof. Such materials are more fully described in U.S. Pat. No. 5,460,592 which is hereby incorporated by reference. Further exemplary bio-absorbable polymers and polymer compositions that can be used in this invention are described in the following patents which are hereby incorporated by reference: U.S. Pat. No. 4,052,988 which discloses compositions comprising extruded and oriented filaments of polymers of p-dioxanone and 1,4-dioxepan-2-one; U.S. Pat. No. 3,839,297 which discloses compositions comprising poly[L(−)lactide-co-glycolide] suitable for use as absorbable sutures; U.S. Pat. No. 3,297,033, which discloses the use of compositions comprising polyglycolide homopolymers as absorbable sutures; U.S. Pat. No. 2,668,162, which discloses compositions comprising high molecular weight polymers of glycolide with lactide; U.S. Pat. No. 2,703,316m which discloses compositions comprising polymers of lactide and copolymers of lactide with glycolide; U.S. Pat. No. 2,758,987, which discloses compositions comprising optically active homopolymers of L(−) lactide i.e. poly L-Lactide; U.S. Pat. No. 3,636,956, which discloses compositions of copolymers of L(−) lactide and glycolide having utility as absorbable sutures; U.S. Pat. No. 4,141,087, which discloses synthetic absorbable crystalline isomorphic copolyoxylate polymers derived from mixtures of cyclic and linear diols; U.S. Pat. No. 4,441,496, which discloses copolymers of p-dioxanone and 2,5-morpholinediones; U.S. Pat. No. 4,452,973, which discloses poly(glycolic acid)/poly (oxyalkylene) ABA triblock copolymers; U.S. Pat. No. 4,510,295, which discloses polyesters of substituted benzoic acid, dihydric alcohols, and glycolide and/or lactide; U.S. Pat. No. 4,612,923, which discloses surgical devices fabricated from synthetic absorbable polymer containing absorbable glass filler; U.S. Pat. No. 4,646,741 which discloses a surgical fastener comprising a blend of copolymers of lactide, glycolide, and poly(p-dioxanone); U.S. Pat. No. 4,741,337, which discloses a surgical fastener made from a glycolide-rich blend of polymers; U.S. Pat. No. 4,916,209, which discloses bio-absorbable semi-crystalline depsipeptide polymers; U.S. Pat. No. 5,264,540, which discloses bio-absorbable aromatic polyanhydride polymers; and U.S. Pat. No. 4,689,424, which discloses radiation sterilizable absorbable polymers of dihydric alcohols. If desired, to further increase the mechanical stiffness of the molded embodiments of the present invention, bio-absorbable polymers and polymer compositions can include bio-absorbable fillers, such as those described in U.S. Pat. No. 4,473,670 (which is incorporated by reference) which discloses a composition of a bio-absorbable polymer and a filler comprising a poly(succinimide); and U.S. Pat. No. 5,521,280 (which is incorporated by reference) which discloses bio-absorbable polymers and a filler of finely divided sodium chloride or potassium chloride.

The final hardness of a polymer of the therapeutic members of the present invention should preferably be in a range from 20 to 80 durometer and more preferably in the range of 20-40 durometer. However, members with other hardnesses are also within the scope of the present invention. Where the material **104** is bio-absorbable, the bio-absorbable material should preferably be absorbed in living tissue in a period of time of from about 70 to about 120 days, but can be manufactured to be absorbed anywhere in a range from 1 week to 1 year or more, depending on the therapeutic plan for a specific patient.

The material **104** should also be bio-compatible, whether or not it is bio-absorbable. The material **104** may also be bio-adhesive.

In accordance with an embodiment of the present invention, the minimum thickness of the material **104** that encapsulates the source **102** should be about 0.002 inches. Such minimum thickness would occur at locations where there is not a protrusion. The preferred thickness of the material **104** where there is not a protrusion is about 0.004 inches. As mentioned above, the protrusions preferably extend at least 0.002 inches so that they can sufficiently grip into patient tissue. Such extension of the protrusions is that which is beyond the underlying thickness of the material **104**. The protrusions are preferably separated from one another a sufficient distance such that the voids formed between the protrusions allow patient tissue to occupy these voids to reduce the tendency for the therapeutic member, and the radioactive source **102** therein, to migrate or rotate. Preferably, these voids or spaces between protrusions are at least 0.010 inches, so that patient tissue can fit into these spaces. The overall dimensions of the therapeutic members of the present invention are limited by the inner diameter of the needle that is to be used to implant the members. For example, the larger the inner diameter of the needle, the more the protrusions can extend.

The term polymer, as used herein, is also meant to include copolymers. Table 2 below provides examples of bio-absorbable polymers suitable for use in producing embodiments of the present invention, along with specific characteristics (e.g., melting points) of the various polymers. A further discussion of such bio-absorbable polymers can be found in an article by John C. Middleton and Arthur J. Tipton entitled "Synthetic Biodegradable Polymers as Medical Devices," published March 1998 in *Medical Plastics and Bio-materials*, which article is incorporated herein by reference.

TABLE 2

Biodegradable polymers, properties and degradation time

POLYMER	MELTING POINT (° C.)	GLASS-TRANSITION TEMP (° C.)	MOD-ULUS Gpa)[a]	DEGRADA-TION TIME (MONTHS)[b]
PGA	225-230	35-40	7.0	6 to 12
LPLA	173-178	60-65	2.7	>24
DLPLA	Amorphous	55-60	1.9	12 to 16
PCL	58-63	(−65)-(−60)	0.4	>24
PDO	N/A	(−10)-0	1.5	6 to 12
PGA-TMC	N/A	N/A	2.4	6 to 12
85/15 DLPLG	Amorphous	50-55	2.0	5 to 6
75/25 DLPLG	Amorphous	50-55	2.0	4 to 5
65/35 DLPLG	Amorphous	45-50	2.0	3 to 4
50/50 DLPLG	Amorphous	45-50	2.0	1 to 2

[a]Tensile or flexural modulus.

[b]Time to complete mass loss. Rate also depends on part geometry.

FIG. **9** illustrates an exemplary applicator **900**, often referred to as a MICK™ applicator, that can be used to implant the therapeutic members of the present invention at variable spaced locations within a patient's body. Such an applicator **900** is available from Mick Radio-Nuclear Instruments, Inc., of Mount Vernon, N.Y.

The applicator **900** includes a hollow needle **912** insertable into the patient's body, a needle chuck **913** for releasably holding the needle **912**, a magazine **914** for holding and dispensing therapeutic members of the present invention (containing seeds or other radioactive sources) into the needle chuck **913**, a main barrel **916** connected to the needle chuck **913**. Also shown in FIG. **9** is a stylet **917** extendable through the main barrel **916**, the needle chuck **913**, and a bore of the needle **912**. The applicator **900** also includes a base frame member along which the needle **912**, the needle chuck **913**, the magazine **914** and the main barrel **916** are slidably mounted. The frame member includes an abutment end **922** adapted to abut a surface of the patient's body or a template (not shown) fixed with respect to the body, a barrel collar **924** through which the main barrel **916** is slidable, and two rods **926** (only one can be seen in the side view of FIG. **9**) extending between and fixedly attached to the abutment end **922** and the collar **924**. The collar **924** is equipped with a finger ring **928** for receiving a finger of a user.

The applicator **900** is designed to allow the needle **912** to be moved in different increments with respect to the base frame. For this purpose, the main barrel **916** includes rows of detents or indentations **952** that extend along the length of the barrel **916**, with each row having different indentation spacing (only one row is shown in FIG. **9**). For example, the applicator **900** can have a first row of indentations spaced at 3.75 mm, a second row of indentations spaced at 4.0 mm, a third row of indentations spaced at 5.0 mm, a fourth row of indentations spaced at 5.5 mm, and a fifth row of indentations at 6.0 mm. These spacings can be changed as desired by using an applicator having a main barrel with other indentation spacings.

The barrel collar **924** includes a fixed portion **955** and a spacing dial **956** rotatably mounted on the fixed portion **955**. An operator can turn the dial **956** relative to the fixed portion **955** to select one of the rows or series of indentations.

The magazine **914** includes a magazine head **933** and a cartridge **934** in which therapeutic members of the present invention can be stacked parallel to each other. A spring-loaded magazine plunger **938** is biased against the therapeutic members (each of which includes a radioactive source **102**) at the upper end of the magazine **914** to facilitate movement of the therapeutic members into the needle chuck **913** and to provide an indication to the operator that a therapeutic member has been dispensed from the cartridge **934**.

The cartridge **934** can be preloaded with a plurality of therapeutic members of the present invention (e.g., up to 20 members, each with a radioactive source **102**) and then screwed into the magazine head **933**. The cartridge **934** can be keyed to the needle chuck **913** to prevent its incorrect insertion into the needle chuck **913**.

In the operation, the needle **912** is inserted into a patient in an area where a single radioactive source or row of radioactive sources is to be implanted. Then, the needle chuck **913** of the body of the applicator **900** is coupled with the protruding end of the needle **912** to prepare the applicator **900** for use. An initial radioactive source spacing can be set by adjusting the spacing dial **956** to select a particular row of indentations **952** on the main barrel **916** corresponding to the desired spacing. The stylet **917**, which is initially fully extended in the needle **912**, is then retracted from the needle **912** and the needle chuck **913**, enabling a therapeutic member (including a radioactive source) from the magazine **914** to be positioned in the chuck **913** for movement into the needle **912**. When the style **917** is retracted, the therapeutic member is moved into the chuck and the extended magazine plunger **938** will move further into the magazine **914**, which will indicate to the operator that a member has been positioned for transfer into the needle **912**. The stylet **917** is then pushed through the barrel **916** against the therapeutic member, forcing the member through the needle **912** and into the patient's body.

After a first member (including a radioactive source) has been implanted, the needle **912** is withdrawn from the patient's body by a particular distance so that the next radioactive source to be implanted is spaced apart from the first

radioactive source. Then, the stylet **917** is again retracted to enable the next therapeutic member (with a radioactive source) from the magazine **914** to be positioned for movement into the needle **912**. The stylet **917** is then advanced through the needle **912** to force the therapeutic member into the patient's body at a desired distance away from the first member. This procedure is repeated for subsequent therapeutic member implants. Additional details of this process and the applicator **900** can be found in U.S. Pat. No. 5,860,909, which is incorporated herein by reference. This is just one example of a device that can be used to implant therapeutic members of the present invention. Other devices may also be used, while still being within the scope of the present invention. For example, rather than using cartridges as described above, therapeutic members of the present invention (and optionally, spacers therebetween) can be preloaded into a needle that is used to implant a row of such members (and optionally, spacers therebetween) in a single needle track.

The conventional stylet **917** that is used with an applicator, such as a Mick™ applicator, is made using a solid wire. However, this can result in the mislocation of the sources in the needle track due to vacuum phenomena occurring as the needle and stylet are withdrawn. To overcome this problem, the stylet **917** is preferably a vented stylet that includes a vent that extends the length of the stylet, as described in U.S. Pat. No. 6,554,760, which is incorporated herein by reference.

Embodiments of the present invention, as described above, are directed to therapeutic members that include protrusions and/or anchor mechanisms that reduce the tendency for the therapeutic member and the radioactive source therein to migrate and rotate within a patient's body after implantation. Embodiments of the present invention are also directed to cartridges, similar to 934, that are pre-loaded with such therapeutic members.

The above mentioned embodiments of the present invention relate to therapeutic members that include a single radioactive source (a single seed, rod or coil). It is also possible that embodiments of the present invention can be used together with elongated members known as strands that include multiple radioactive sources that are spaced from one another, e.g., as described in U.S. patent application Ser. No. 10/035,083, which was filed on Dec. 28, 2001, and which is incorporated herein by reference. More specifically, one or more therapeutic member as described in FIGS. **1**-**7**, which each include a single radioactive source **102**, can be used together with one or more strand that includes multiple radioactive sources.

For example, a single needle can be loaded with a therapeutic member having a single radioactive source as well as with a strand having multiple radioactive sources, thereby allowing for implantation of both during the same procedure that include insertion and removal of the needle. This would be useful, e.g., where a first radioactive source in a row of radioactive sources is to be located near a patient's bladder or urethra. If a strand of radioactive sources were being implanted, and the end of the strand were inserted too far and into the patient causing it to enter the bladder or urethra, then the entire strand would have to be removed from the patient. However, if the first radioactive source implanted was within a therapeutic member of the present invention, and that radioactive source got into the bladder or urethra, then it would be possible to remove the single first radioactive source without removing strand that followed the first radioactive source.

As mentioned above, seeds (or other radioactive sources) are sometimes implanted into a patient by preloading a hollow needle with seeds and spacers that are used to maintain a desired distance between a row of seeds, e.g., as described in U.S. Pat. No. 6,554,760, which is incorporated herein by reference. The seeds and spacers are deployed from the hollow needle using a stylet, which preferably includes a radial vent that extends the length of the stylet, to reduce the mislocation of the radioactive sources in the needle track due to vacuum phenomena occurring as the needle and stylet are withdrawn. In such implants, the first and last seeds are the most likely seeds to migrate and/or rotate, however the other seeds, as well as the spacers, may also migrate and/or rotate within the needle track. To reduce migration of the seeds, therapeutic members of the present invention can be used. That is, a seed can be encapsulated by a material that includes protrusions that will resist the migration and rotation of the seed therein. In another embodiment, protrusions can be added to the spacers that are used to maintain the desired distances between the radioactive sources. Such spacers with protrusions can be made in manners similar to those explained above. For example, protrusions can be added to preexisting spacers (e.g., cylindrical spacers) by encapsulating the spacer with a material within which protrusions are formed. Alternatively, spacers can be manufactured to include protrusions. Such spacers can be formed, e.g., using an embossing mold, or by machining, crimping or otherwise forming protrusions in an outer surface of the spacers. The spacers with protrusions can be used together with therapeutic members having protrusions, or with radioactive sources that do not have protrusions. When used with radioactive sources not having protrusions, the spacers with protrusions would preferably be located at both longitudinal ends of the radioactive sources, to thereby trap the radioactive sources in place. For example, if five radioactive seeds were to be implanted in a single needle track, six such spacers can be used (i.e., four spacers each of which separate pairs of seeds, and a spacer prior to the first seed, and a spacer following the last seed). The spacers that are located between seeds preferably include protrusions similar to those explained with reference to FIGS. **1**-**7**. The spacers that are located prior to the first seed and following the last seed in the needle track can include protrusions similar to those explained with reference to FIGS. **1**-**7**, or can include anchor mechanisms similar to those described above with reference to FIGS. **8**A-**8**D. The spacers with protrusions can be made entirely from a bio-absorbable material, examples of which are listed above. Alternatively, the spacers with protrusions can be made from a non-bio-absorbable material which is bio-compatible. In still another embodiment, the spacer is made of a body that is bio-compatible but non-bio-absorbable, which is encapsulated within a bio-absorbable material that is used to form the protrusions.

FIGS. **10**A-**10**C illustrate a spacer **1000** according to another embodiment of the present invention. As shown in FIGS. **10**A-**10**C, the spacer **1000** includes two halves **1002** and **1004** that are connected by a living hinge **1006**. The halves **1002** and **1004** are shown as being half cylinders, but other shapes are also possible. The living hinge **1006** is biased such that after the spacer is folded into its closed position (FIG. **10**B), the spacer tends to open up such that a gap **1008** forms between the two halves (FIG. **10**C). This can be accomplished, e.g., by molding the two halves **1002** and **1004** and the living hinge **1006** in the open position shown in FIG. **10**A. The two haves **1002** and **1004** can then be folded toward one another along the living hinge **1006** to place the spacer **1000** in the closed position shown in FIG. **10**B, at which point the spacer can be inserted into a hollow needle used to implant spacers and radioactive sources in a patient. Once implanted in the patient, the spacer **1000** will tend to open or unfold along the living hinge **1006**, causing an outer surface of the

spacer **1000** to thereby engage the patient tissue that surrounds the spacer **1000**. This engagement with patient tissue will cause the spacer to resist migration and rotation. To further resist migration and rotation, protrusions, such as those discussed above, can be added to the outer surface of the spacer. The spacer **1000** can be made entirely from a bio-absorbable material, examples of which are listed above. Alternatively, the spacer **1000** can be made from a non-bio-absorbable material which is bio-compatible.

In accordance with other embodiments of the present invention, an entire strand **1100** that includes multiple radioactive sources (e.g., seeds) **102**, or portions of the strand **1100**, can include the protrusions of the present invention, e.g., as shown in FIG. **11**. Because a typical strand includes polymeric material that attaches multiple radioactive sources to one another at desired spacings, a strand is not as susceptible to migration and twisting as loose radioactive sources. Nevertheless, it is still possible that that radioactive sources within the strands, especially the radioactive sources located near the distal ends of the strand, can migrate and/or twist. By including protrusions that extend from the strand, the tendency for the strand or portions of the strand to migrate and/or twist can be reduced. Such protrusions can extend from portions of the strand where radioactive sources are located, but can alternatively or additionally extend from other portions of the strand, such as the portions of the strand between the radioactive sources.

In another embodiment of the present invention, the anchor mechanism (e.g., **810**) disclosed above with reference to FIGS. **8**A-**8**E can be located at one or both longitudinal distal ends of a strand **1200** that includes multiple radioactive sources **102**, e.g., as shown in FIG. **12**.

The strands **1100** and **1200** can be manufactured using similar molding processes that were used to produce the therapeutic members of the present invention. For example, to produce the strand **1100**, radioactive sources **102** can be placed into an embossing mold that allows the radioactive sources **102** to be spaced at the appropriate intervals in a cavity of the embossing mold that is shaped to the desired final dimensions, including the protrusions, of the strand. All the spacings between the radioactive sources **102** can be of different lengths, if the preoperative therapeutic plan so specifies. Spacers (not shown) can be placed between radioactive sources **102** to keep a desired spacing between the radioactive sources, if desired. Alternative means for maintaining the spacings between adjacent radioactive sources may be used, as is known in the art. The strand **1200** can be manufactured in a similar fashion as was just described, and as was described above with reference to FIGS. **8**A-**8**E.

In accordance with specific embodiments of the present invention, a resulting strand (e.g., **1100** or **1200**) is a single solid monofilament of a polymer with the radioactive sources **102** spaced within the monofilament and encapsulated at the appropriate intervals. The strand is preferably axially flexible. However, the strand preferably has sufficient column strength along its longitudinal axis so that the strand can be urged out of a hollow needle without the strand folding upon itself. Again, the intervals can be selected to be any distance or combination of distances that are optimal for the treatment plan of the patient.

In another embodiment, a strand can be made by inserting (i.e., pushing) radioactive sources and spacers through an opening in one end of an elongated hollow tube of bio-absorbable material. Additional details of a seed pusher that can be used in this process are described in U.S. Pat. No. 6,761,680, which was incorporated herein by reference above. The protrusions of the present invention can be formed on the outer surface of the hollow tube prior to or after the insertion of the radioactive sources and spacers.

In a further embodiment, a strand can be constructed using a pair of pre-formed elongated members of bio-absorbable material that are shaped like half-shells, as described in U.S. Pat. No. 6,761,680, which is incorporated herein by reference. The two half-shells can be separate from one another. Alternatively, the two half shells can be connected by a living hinge along their length. The radioactive sources and spacers are placed within a first one of half-shells. The second half-shell is then mated with the first half-shell, and the half-shells are fused together (e.g., using ultrasonic welding or heat), thereby fixing the radioactive sources and spacers inside. The protrusions of the present invention can be formed on the outer surface of such half-shells before or after the radioactive sources and spacers are placed therein.

In still another embodiment, a strand can be made by inserting the seeds and spacers into a tube of braded bio-absorbable material. Additional details of such a braded bio-absorbable tube are described in U.S. Pat. No. 5,460,592, which is incorporated herein by reference. Protrusions can then be added, e.g., by slipping doughnut shaped rings over the breaded material. Such doughnut shaped rings can also be slipped over any other type of strand that has a generally cylindrical outer surface.

In another embodiment, one or more spacers **1000** that are biased to open (as described above with reference to FIG. **10**) can be incorporated into a strand **1300**, as shown in FIG. **13**. The spacers **1000** can be incorporated into the strand **1300** in various manners, such as by insert molding them into the strand. When the strand **1300** including such spacers **1000** is inserted into a hollow needle, the spacers **1000** will be kept in their closed position by the inner wall of the needle. However, once implanted in a patient, the spacers **1000** will at least partially open and engage the tissue surrounding the spacer, thereby anchoring the entire strand **1300**. More generally, portions of the strand **1300** can be biased such that they at least partially open or expand to engage tissue surrounding the strand. As shown in FIG. **13**, the portions of the strand that open to engage surrounding tissue can be at one or both distal ends of the strand and/or at locations between the distal ends. In FIG. **13**, the living hinges **1006** are shown as being along the length of the strand **1300**. However, this need not be the case. For example, a living hinge can be located at one or both of the longitudinal ends of the strand, and thus be perpendicular to the length of the strand.

Embodiments of the present invention are also directed to radiopaque markers that include protrusions and/or anchor mechanisms, similar to those described above, to reduce the tendency of the markers to migrate and rotate within a patient's body after implantation. Such markers can be made entirely or partially of a radiopaque material. Such a radiopaque material is often a dense, high atomic number material, such as gold or tungsten, which can block the transmission of X-rays or other radiation so that the markers can be detected using X-ray or other radiation imaging techniques. For example, a marker can be a ball, rod or wire constructed from gold or tungsten. Alternatively, the marker can be a container that includes a ball, rod or wire of radiopaque material, or a container at least partially coated with a radiopaque material. One commercially available marker is marketed under the trademark VISICOIL and is available from RadioMed Corporation of Tyngsboro, Mass. These are just a few examples of such markers. One of ordinary skill in the art will understand that other markers are also possible. To add the protrusions and/or anchor mechanisms to an existing marker, the marker can be encapsulated in a polymeric material within

which protrusions and/or anchor mechanisms are formed, in any of the manners described above. Alternatively, a marker can be manufactured to include protrusions and/or anchor mechanisms.

The markers can be implanted within a patient that will be undergoing external beam radiation therapy. If the patient is to also undergo brachytherapy, then the markers can implanted at the same time that radiation sources are being implanted into the patient. In specific embodiments, radiopaque markers can be included in spacers and/or strands of the present invention. By including a marker within a spacer or strand that includes protrusions and/or anchor mechanisms, the marker therein will also be resistant to migration and rotation.

In another embodiment, shown in FIGS. **14**A-**14**D, an anchor mechanism **1400** includes a sleeve **1404** to which are attached, by living hinges **1406**, wings **1408**. The wings **1408** are shown as being generally rectangular, but can have other shapes. Two wings **1408** are shown, but more are less can be used. The sleeve **1404** is intended to be placed around an underlying structure **1402**, which can be a radioactive source (e.g., seed, rod or coil), a thermal ablation implant, a spacer, a strand, or a radiopaque marker. Each living hinge **1406** is biased in its open position (FIGS. **14**A and **14**B), such that after the wings **1408** are folded into their closed positions (FIGS. **14**C and **14**D), the wings **1408** will tend to open. This can be accomplished, e.g., by molding the anchor mechanism **1400** in the open position shown in FIGS. **14**A and **14**B. After being placed around an underlying structure **1402**, the wings **1408** can then be folded inward along the living hinges **1406** to be in the closed position shown in FIGS. **14**C and **14**D. When in the closed position, the entire structure, including the underlying structure **1402** and anchor mechanism **1400**, can be inserted into a hollow needle used to implant the structure in a patient. The inner wall of the hollow needle will keep the wings **1408** in their closed position. Because of the biasing of the living hinges **1406**, once implanted in the patient, the wings **1408** will tend to open or unfold along the living hinges **1406**, causing the wings **1408** to thereby engage the surrounding patient tissue. This engagement will resist migration and rotation of the structure **1402**. To further resist migration and rotation, protrusions, such as those discussed above, can be added to the wings **1408** and/or sleeve **1404**. The anchor mechanism **1400** can be made entirely from a bio-absorbable material, examples of which are listed above. Alternatively, the anchor mechanism can be made from a non-bio-absorbable material which is bio-compatible.

The previous description of the preferred embodiments is provided to enable any person skilled in the art to make or use the embodiments of the present invention. While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention.

What is claimed is:

1. An implant configured and adapted to be implanted in a patient at least one of between radioactive seeds and containing one or more radioactive seeds, comprising:

a polymeric cylindrical body with a longitudinal axis,

wherein a first bullet shaped polymeric rounded end and a second bullet shaped polymeric rounded end extend from said polymeric cylindrical body, said first bullet shaped polymeric rounded end including a first inwardly facing sidewall which is perpendicular to the longitudinal axis, said second bullet shaped polymeric rounded end including a second inwardly facing sidewall which is perpendicular to the longitudinal axis, with the first inwardly facing sidewall facing said second inwardly facing sidewall;

a first polymeric rib and a second polymeric rib completely encircling said polymeric cylindrical body and with said first and second polymeric ribs located between the first inwardly facing sidewall and the second inwardly facing sidewall, with said first polymeric rib spaced from said first bullet shaped polymeric rounded end, and said second polymeric rib spaced from said first polymeric rib, and said second bullet shaped polymeric rounded end spaced from said second polymeric rib;

wherein said first bullet shaped polymeric rounded end, said second bullet shaped polymeric rounded end, said first polymeric rib and said second polymeric rib all have the same circumference;

said first polymeric rib including third and fourth sidewalls that are perpendicular to said longitudinal axis;

said second polymeric rib including fifth and sixth sidewalls that are perpendicular to said longitudinal axis;

wherein said implant is adapted to be urged out of a needle to be implanted in a patient and wherein said implant is adapted to receive tissue between the first inwardly facing sidewall and said third sidewall, between said fourth sidewall and said fifth sidewall, and between said sixth sidewall and said second inwardly facing sidewall, when the implant is implanted in a patient in order to reduce the tendency of the implant to migrate within the patient's body.

2. The implant of claim **1**, wherein a drug is at least one of coated onto said polymeric body and included in polymeric material of the polymeric body.

3. The implant of claim **1**, wherein said implant is a spacer and is adapted to be positioned between other implants.

4. An implant configured and adapted to be implanted in a patient at least one of between radioactive seeds and containing one or more radioactive seeds comprising:

a cylindrical polymeric body with a longitudinal axis,

a first bullet shaped polymeric rounded end and a second bullet shaped polymeric rounded end extending from said polymeric body;

said first bullet shaped polymeric rounded end including a first inwardly facing sidewall which is perpendicular to the longitudinal axis;

said second bullet shaped polymeric rounded end including a second inwardly facing sidewall which is perpendicular to the longitudinal axis with the first inwardly facing sidewall facing said second inwardly facing sidewall;

a first polymeric rib, said first polymeric rib completely encircling the cylindrical polymer body, said first polymeric rib located between the first inwardly facing sidewall and the second inwardly facing sidewall, with said first bullet shaped polymeric rounded end spaced from said first polymeric rib and said first polymeric rib spaced from said second bullet shaped polymeric rounded end;

wherein said first bullet shaped polymeric rounded end, said second bullet shaped polymeric rounded end, and said first polymeric rib all have the same circumference;

said first polymeric rib including third and fourth sidewalls that are perpendicular to said longitudinal axis; and

wherein said implant is adapted to be urged out of a needle to be implanted in a patient and wherein said implant is adapted to receive tissue between the first inwardly facing sidewall and said third sidewall and between said fourth sidewall and said second inwardly facing sidewall

when the implant is implanted in a patient in order to reduce the tendency of the implant to migrate within the patient's body.

5. The implant of claim **4**, wherein a drug is at least one of coated onto said polymeric body and included in polymeric material of the polymeric body.

6. The implant of claim **4**, wherein said implant is a spacer and is adapted to be positioned between other implants.

7. An implant configured and adapted to be implanted in a patient at least one of between radioactive seeds and containing one or more radioactive seeds, comprising:

a longitudinal axis;

a polymeric body with opposite ends;

a pair of bullet shaped rounded ends, the rounded ends capping opposite respective ends of the polymeric body;

wherein the pair of bullet shaped rounded ends comprise polymer;

wherein each of the bullet shaped rounded ends includes a sidewall perpendicular to the longitudinal axis; and

at least one rib encircling the polymeric body, the at least one rib arranged between the pair of bullet shaped rounded ends capping the opposite ends of the polymeric body;

wherein said pair of bullet shaped rounded ends and said at least one rib all have the same circumference;

wherein the at least one rib includes a surface, connected between a pair of additional sidewalls, the additional sidewalls being perpendicular to the longitudinal axis and perpendicular to the surface of the at least one additional rib; and

wherein the implant is adapted to receive tissue between the additional sidewalls of the at least one rib and sidewalls of the pair of bullet shaped rounded ends capping opposite ends of the polymeric body when the implant is implanted in a patient's body to reduce a tendency of the implant to migrate within the patient's body after implantation.

8. The implant of claim **7**, wherein a drug is at least one of coated onto said polymeric body and included in polymeric material of the polymeric body.

9. The implant of claim **7**, wherein said implant is a spacer and is adapted to be positioned between other implants.

10. An implant configured and adapted to be implanted in a patient at least one of between radioactive seeds and containing one or more radioactive seeds, comprising:

a polymeric body with opposite ends with a longitudinal axis;

a pair of bullet shaped rounded ends extending from the polymeric body, the rounded ends capping the opposite respective ends of the polymeric body so that the implant is adapted to be positioned within and urged through a needle;

wherein the pair of bullet shaped rounded ends comprise polymer;

wherein each of the rounded ends includes a sidewall perpendicular to the longitudinal axis; and

at least one rib defined by the outer surface of the polymeric body encircling the polymeric body, the at least one rib arranged between the pair of rounded ends capping opposite ends of the polymeric body;

wherein the at least one rib comprise polymer;

wherein said pair of bullet shaped rounded ends and said rib all have the same circumference;

wherein the at least one rib includes a surface connected between a pair of additional sidewalls, the additional sidewalls being perpendicular to the longitudinal axis of the polymeric body and perpendicular to the outer surface of the at least one rib;

wherein the implant is adapted to receive tissue between the additional sidewalls of the at least one rib and the sidewalls of the pair of bullet shaped rounded ends capping opposite ends of the polymeric body when the implant is implanted in a patient's body to reduce a tendency of the implant to migrate within the patient's body after implantation; and

wherein the pair of bullet shaped rounded ends and the at least one rib are defined by variations in a thickness of the polymeric body.

11. The implant of claim **10**, wherein a drug is at least one of coated onto said polymeric body and included in polymeric material of the polymeric body.

12. The implant of claim **10**, wherein said implant is a spacer and is adapted to be positioned between other implants.

13. An implant configured and adapted to be implanted in a patient at least one of between radioactive seeds and containing one or more radioactive seeds, comprising:

a polymeric body with a longitudinal axis and with opposite ends;

a pair of bullet shaped rounded ends extending from the polymeric body, the rounded ends capping opposite ends of the polymeric body;

wherein each of the bullet shaped rounded ends includes a sidewall perpendicular to the longitudinal axis; and

at least one rib extending from the polymeric body and encircling the polymeric body, the at least one rib arranged between the pair of bullet shaped rounded ends capping opposite ends of the polymeric body;

wherein said pair of bullet shaped rounded ends and said at least rib all have the same circumference;

wherein the at least one rib includes a pair of additional sidewalls perpendicular to the longitudinal axis; and

wherein the implant is adapted to receive tissue between the additional sidewalls of the at least one rib and the sidewalls of the pair of bullet shaped rounded ends capping opposite ends of the polymeric body when the implant is implanted in a patient's body to reduce a tendency of the implant to migrate within the patient's body after implantation.

14. The implant of claim **13**, wherein a drug is at least one of coated onto said polymeric body and included in polymeric material of the polymeric body.

15. The implant of claim **13**, wherein said implant is a spacer and is adapted to be positioned between other implants.

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